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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0308; Project Identifier MCAI-2020-00594-R; Amendment 39-21619; AD 2021-13-14]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Helicopters Deutschland GmbH (AHD) Model BO-105A, BO-105C, BO-105S, and BO-105LS A-3 helicopters. This AD was prompted by an uncommanded activation of the hoist cable cutter function on an MBB-BK117 C-1 helicopter, which prompted a design review of the BO105 hoist control grip with coiled cable. This AD requires inspections of the hoist control grip with coiled cable and deactivation of the hoist cutter function, 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 August 17, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 17, 2021.

ADDRESSES: 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 on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0308.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0308; 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, 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:

Blaine Williams, Aerospace Engineer, Cabin Safety & Environmental Systems Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627-5371; email blaine.williams@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2015-0017, dated February 4, 2015 (EASA AD 2015-0017), to correct an unsafe condition for certain Airbus Helicopters Deutschland GmbH Model BO105 A, BO105 C, BO105 D, BO105 S, and BO105 LS A-3 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 Model BO-105A, BO-105C, BO-105S, and BO-105LS A-3 helicopters. The NPRM published in the **Federal Register** on April 19, 2021 (86 FR 20341). The NPRM was prompted by an uncommanded activation of the hoist cable cutter function on an MBB-BK117 C-1 helicopter which prompted a design review of the BO105 hoist control grip with coiled cable. The NPRM proposed to require

accomplishing the actions specified in EASA AD 2015-0017, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under “Differences Between this AD and the EASA AD.”

The FAA is issuing this AD to prevent uncommanded cutting of the hoist cable and subsequent injury to persons being lifted by the hoist and injury to persons on the ground. See the EASA AD 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 and the public interest require adopting this final rule as proposed in the NPRM.

Related Service Information Under 14 CFR Part 51

For Model BO105 C, BO105 D, BO105 S, and BO105 LS A-3 helicopters, EASA AD 2015-0017 specifies to perform an initial and recurring inspections of the hoist control grip with coiled cable of the hoist and depending on the results, replacing the hoist control grip with coiled cable with a serviceable part. EASA AD 2015-0017 also specifies to replace any hoist control grip with coiled cable that has exceeded 10 years since first installation or since last overhaul and to deactivate the cable cutter function in accordance with referenced service information.

EASA AD 2015-0017 also specifies to not operate the hoist on any of the Model BO105 A, BO105 D, variant BO105 D, and BO105 DS helicopters. For Model BO105 helicopters, except for BO105 D, variant BO105 D, and BO105 DS helicopters, EASA specifies to amend the helicopter flight manual (FM) to incorporate the temporary revision as specified in Table 1 of the EASA AD.

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.

Differences Between This AD and the EASA AD

Where EASA AD 2015–0017 refers to its effective date, this AD requires using the effective date of the FAA AD. Where EASA AD 2015–0017 specifies this unsafe condition for Airbus Helicopters Deutschland GmbH Model BO105 A, BO105 C, BO105 D, BO105 S, and BO105 LS A–3 helicopters, this AD does not include Model BO–105 D helicopters, because this model is not FAA type-certificated. Where EASA AD 2015–0017 specifies replacing an affected part, this AD requires removing the part from service. Where the service information referenced in the EASA AD refers to calendar time for certain actions, this AD uses hours time-in-service instead. The EASA AD allows a tolerance to certain compliance times, whereas this AD does not. The EASA AD requires using service information to accomplish the preflight checks of the control grip with coil cable, whereas this AD requires visually checking the condition of the control grip and coiled cable for mechanical damage including deformed or damaged switches, damaged housing, abrasion, cracks, and cuts instead. The owner/operator (pilot) may perform the required visual checks but must enter compliance with the applicable paragraph of this AD in the helicopter maintenance records in accordance with 14 CFR 43.9(a)(1) through (4) and 91.417(a)(2)(v). A pilot may perform these checks because they only involve visually checking affected control grips with coiled cable. This action can be performed equally well by a pilot or a mechanic. This check is an exception to the FAA's standard maintenance regulations.

Interim Action

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

Costs of Compliance

The FAA estimates that this AD affects 20 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 hoist control grip with coiled cable takes up to one quarter work-hour for an estimated cost of \$21 per helicopter and \$420 for the U.S. fleet, per inspection cycle. Replacing the hoist control grip takes about 1 work-hour and parts cost \$1,956 for an

estimated cost of \$2,041 per helicopter. Replacing the coiled cable takes about 2 work-hours and parts cost \$1,858 for an estimated cost of \$2,028 per helicopter. Deactivation of the cable cutter function takes about 1 work hour and parts cost about \$26 for an estimated cost \$111 per hoist control grip.

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:

2021–13–14 Airbus Helicopters

Deutschland GmbH (AHD): Amendment 39–21619; Docket No. FAA–2021–0308; Project Identifier MCAI–2020–00594–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 17, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH (AHD) Model BO–105A, BO–105C, BO–105S, and BO–105LS A–3 helicopters, certificated in any category, as identified in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2015–0017 dated February 4, 2015 (EASA AD 2015–0017).

(d) Subject

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

(e) Reason

This AD was prompted by uncommanded activation of the hoist cable cutter function on an MBB–BK117 C–1 helicopter which prompted a design review of the BO105 hoist control grip with coiled cable. The FAA is issuing this AD to prevent uncommanded cutting of the hoist cable and subsequent injury to persons being lifted by the hoist and 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 2015–0017.

(h) Exceptions to EASA AD 2015–0017

(1) Where EASA AD 2015–0017 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Note 1 of EASA AD 2015–0017 specifies a non-cumulative compliance time tolerance of 10% for certain required compliance times, this AD does not allow this tolerance.

(3) Where paragraph (1) of EASA AD 2015–0017 specifies a compliance time of “not to exceed 30 days”, this AD requires a compliance time of within 13 hours time-in-service.

(4) Where paragraph (4) of EASA AD 2015–0017 specifies a compliance time of “within

9 months”, this AD requires a compliance time of within 108 hours time-in-service.

(5) Where paragraph (5) of EASA AD 2015–0017 specifies a compliance time of “within 3 months”, this AD requires a compliance time of within 36 hours time-in-service.

(6) Where paragraph (3) of EASA AD 2015–0017 specifies replacing a part with a serviceable part, this AD requires removing the part from service.

(7) Where the service information referenced in EASA AD 2015–0017 specifies to use tooling, equivalent tooling may be used.

(8) Where the service information referenced in paragraph (2) of EASA AD 2015–0017 specifies a visual check of the control grip coiled cable, this AD requires, before next flight after the effective date of this AD involving a hoist operation, visually checking the control grip with coiled cable for mechanical damage including deformed or damaged switches, damaged housing, abrasion, cracks, and cuts. These visual checks may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(9) Where EASA AD 2015–0017 refers to November 10, 2014, the effective date of EASA AD 2014–0235, this AD requires using the effective date of this AD.

(10) The “Remarks” section of EASA AD 2015–0017 does not apply to this AD.

(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) 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

For more information about this AD, contact Blaine Williams, Aerospace Engineer, Cabin Safety & Environmental Systems Section, Los Angeles ACO Branch, Compliance & Airworthiness Division, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5371; email blaine.williams@faa.gov.

(k) 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 2015–0017, dated February 4, 2015.

(ii) [Reserved]

(3) For EASA AD 2015–0017, 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–2021–0308.

(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 fedreg.legal@nara.gov, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on June 16, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–14778 Filed 7–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1033; Project Identifier MCAI–2020–01393–R; Amendment 39–21622; AD 2021–13–17]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–17–01, which applied to certain Airbus Helicopters Model AS332L2 and EC225LP helicopters. AD 2017–17–01 required repetitive inspections of the main rotor blade (MRB) attachment pins. This AD continues to require the repetitive inspections of the MRB attachment pins, and also requires repetitive measurement of the attachment pin chamfer at certain intervals after corrosion removal, as specified in a European Aviation Safety Agency (now European Union Aviation

Safety Agency) (EASA) AD, which is incorporated by reference. This AD was prompted by the FAA’s determination that it is necessary to measure the attachment pin chamfer after corrosion removal, that replacement of an attachment pin after four corrosion removals is no longer necessary, and that all Airbus Helicopters Model AS332L2 and EC225LP helicopters are affected by the unsafe condition. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 17, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 17, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +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 on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–1033.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–1033; 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, 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: Katherine Venegas, Aviation Safety Engineer, Cabin Safety, Mechanical and Environmental Systems Section, Los Angeles ACO Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5353; email: katherine.venegas@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the

European Union, has issued EASA AD 2018–0172, dated August 7, 2018 (EASA AD 2018–0172) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus Helicopters Model AS332L2 and EC225LP helicopters. EASA AD 2018–0172 superseded EASA AD 2015–0016, dated January 30, 2015 (which prompted FAA AD 2017–17–01, Amendment 39–18991 (82 FR 39506, August 21, 2017) (AD 2017–17–01)).

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–17–01. AD 2017–17–01 applied to certain Airbus Helicopters Model AS332L2 and EC225LP helicopters. The NPRM published in the **Federal Register** on November 24, 2020 (85 FR 74931). The NPRM was prompted by the FAA's determination that it is necessary to measure the attachment pin chamfer after corrosion removal, that replacement of an attachment pin after four corrosion removals is no longer necessary, and that all Airbus Helicopters Model AS332L2 and EC225LP helicopters are affected by the unsafe condition. The NPRM proposed to continue to require the repetitive inspections of the MRB attachment pins, as specified in an EASA AD. The NPRM also proposed to require repetitive measurement of the attachment pin chamfer at certain intervals after corrosion removal, as specified in an EASA AD.

The FAA is issuing this AD to address cracked MRB attachment pins which could result in loss of an MRB and subsequent loss of control of the helicopter. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Allow Rework of Corrosion Pits

Air Center Helicopters, Inc. (ACH) and Airbus Helicopters (AH) requested that the FAA allow rework of corrosion pits. ACH disagreed with the FAA's determination to disallow blade pin rework, and stated that scrapping blade pins due to disallowing rework is fiscally irresponsible, due to substantial replacement costs (each main rotor hub has 10 blade pins). ACH pointed out that since the FAA issued AD 2017–17–01, ACH has removed and reworked numerous corrosion pitted EC225 blade

pins from service in accordance with Airbus Helicopters Alert Service Bulletin EC225–05A040. ACH discussed that in many cases the corrosion pitting was nearly undetectable using 10X magnification, and that additional inspections were done using a 0.005 inch ball gauge. ACH also mentioned that visible corrosion pitting was often undetectable using the ball gauge, and pointed out that to ACH, the undetectable corrosion pitting indicated that the blade pin was salvageable with a minimum of rework.

ACH agreed with not allowing blade pin rework in FAA AD 2017–17–01 because Revision 0 of Airbus Helicopters Alert Service Bulletin EC225–05A040 did not specify a method to determine dimensional airworthiness after rework. ACH stated that Revision 1 of Airbus Helicopters Alert Service Bulletin EC225–05A040, included post rework inspection procedures and dimensional criteria for post rework blade pin airworthiness, and that Revision 2 of Airbus Helicopters Alert Service Bulletin EC225–05A040 introduced a maximum radius to the caliper points of 0.6 mm (0.0236 inch) to ensure the point seats properly within the external blade pin blend radius ensuring accurate wall thickness measurements. ACH specified that Airbus Helicopters Alert Service Bulletin EC225–05A040 provides a definitive procedure for inspection and verification of blade pin airworthiness after corrosion pitting rework, and that the procedure was approved by EASA.

ACH and AH argued that the term “corrosion” in Airbus Helicopters Alert Service Bulletin EC225–05A040, is intended to include corrosion pitting. AH pointed out that the service information is currently at Revision 2, that the revision was based on research and feedback from customer reports, and implemented detailed inspection procedures and measurements to determine airworthiness of the blade pins. AH then stated that the FAA did not reflect the intentions of the latest service information.

The FAA disagrees with the request. Although the MCAI and service information specify rework in case corrosion is found, neither clearly address action in the case of corrosion pitting. Corrosion pitting is different than uniform corrosion and can be more dangerous. Additionally, the FAA does not agree with the inference that the intention of the service information is to allow rework of corrosion pits. The FAA has not revised this AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 14 CFR Part 51

EASA AD 2018–0172 specifies procedures for repetitive inspections for corrosion and cracking of the attachment pins and corrective actions if necessary, and repetitive conditional measurement of the thickness of the chamfer of the attachment pins at certain intervals after corrosion removal. Corrective actions include corrosion removal and replacement of the attachment pins. 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.

Differences Between This Proposed AD and the MCAI

EASA AD 2018–0172 requires an inspection of the affected part in accordance with the applicable service information. The service information for Model AS332L2 helicopters and the service information for Model EC225LP helicopters both describe procedures for an inspection for corrosion and cracking of the attachment pins. However, the service information for Model AS332L2 helicopters also describes an inspection of the protective coating of each attachment pin for scratches and missing protective coating and sanding if necessary; the service information for Model EC225LP helicopters does not describe those actions.

Although EASA AD 2018–0172 requires corrective actions if there is corrosion or cracking of the attachment pins, EASA AD 2018–0172 does not require any corrective actions if there is any scratch or any missing protective coating.

This AD requires inspecting the protective coating of each attachment pin for scratches and missing protective coating, and sanding if there is any scratch or any missing protective coating, for all affected helicopters.

EASA AD 2018–0172 requires removing corrosion but does not

provide a corrective action if there are corrosion pits. This AD requires replacing an attachment pin that has any corrosion pitting.

The service information referenced in EASA AD 2018–0172 specifies to do a non-destructive inspection if in doubt

about whether there is a crack; that action is not required by this AD.

The service information referenced in EASA AD 2018–0172 specifies contacting Airbus Helicopters if any attachment pin with a crack is found and returning that part to Airbus

Helicopters; those actions are not required by this AD.

Costs of Compliance

The FAA estimates that this AD affects 28 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
Retained actions from AD 2017-17-01.	1 work-hour × \$85 per hour = \$85 per inspection cycle.	\$0	\$85 per inspection cycle ...	\$2,380 per inspection cycle.

The FAA estimates the following costs to do any necessary on-condition measurements (new action), corrosion removal, and replacements that would

be 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 measurements, corrosion removal, and replacements:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 11 work-hours × \$85 per hour = Up to \$935	Up to \$5,720	Up to \$6,655.

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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:
 ■ a. Removing Airworthiness Directive 2017–17–01, Amendment 39–18991 (82 FR 39506, August 21, 2017); and
 ■ b. Adding the following new airworthiness directive:

2021–13–17 Airbus Helicopters:

Amendment 39–21622; Docket No. FAA–2020–1033; Project Identifier MCAI–2020–01393–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 17, 2021.

(b) Affected ADs

This AD removes AD 2017–17–01, Amendment 39–18991 (82 FR 39506, August 21, 2017) (AD 2017–17–01).

(c) Applicability

This AD applies to all Airbus Helicopters Model AS332L2 and EC225LP helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Codes 6200, Main Rotor System.

(e) Reason

This AD was prompted by a report of three cracked main rotor blade (MRB) attachment pins. The FAA is issuing this AD to address cracked MRB attachment pins which could result in loss of an MRB and subsequent loss of 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 Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0172, dated August 7, 2018 (EASA AD 2018–0172).

(h) Exceptions to EASA AD 2018–0172

(1) Where EASA AD 2018–0172 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2018–0172 refers to February 13, 2015 (the effective date of EASA AD 2015–0016, dated January 30, 2015), this AD requires using September 25, 2017 (the effective date of AD 2017–17–01).

(3) The "Remarks" section of EASA AD 2018–0172 does not apply to this AD.

(4) Where paragraph (1) of EASA AD 2018–0172 specifies to inspect each affected part, for this AD, prior to the inspection for corrosion, inspect the protective coating on the inside of the attachment pin for scratches and missing protective coating. If there is any scratch or any missing protective coating, prior to the inspection for corrosion, sand the attachment pin to remove the varnish in the area depicted as "Area A" in Figure 1 of the "applicable ASB" as defined in EASA AD 2018–0172.

(5) Where paragraph (3) of EASA AD 2018–0172 requires removing corrosion, for this AD, if there is any corrosion pitting, before further flight, replace the affected attachment pin. Do not sand the attachment pin to remove a corrosion pit.

(6) Although the service information referenced in EASA AD 2018–0172 specifies to do a non-destructive inspection if in doubt about whether there is a crack, that action is not required by this AD.

(7) Although the service information referenced in EASA AD 2018–0172 specifies contacting Airbus Helicopters if any attachment pin with a crack is found and returning that part to Airbus Helicopters, those actions are not required by this AD.

(8) Although the service information referenced in EASA AD 2018–0172 specifies discarding certain parts, that action is not required by this AD.

(9) Where EASA AD 2018–0172 refers to flight hours (FH), this AD requires using hours time-in-service.

(i) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(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 Katherine Venegas, Aviation Safety Engineer, Cabin Safety, Mechanical and Environmental Systems Section, Los Angeles ACO Branch, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5353; email: katherine.venegas@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 2018–0172, dated August 7, 2018.

(ii) [Reserved]

(3) For EASA AD 2018–0172, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +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–2020–1033.

(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 fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on June 17, 2021.

Gaetano A. Sciortino,

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

[FR Doc. 2021–14775 Filed 7–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0195; Project Identifier MCAI–2020–00262–R; Amendment 39–21624; AD 2021–13–19]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2014–11–02 for Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. AD 2014–11–02 required repetitively inspecting frame number (No.) 9 for a crack. This AD was prompted by Airbus Helicopters developing a modification that provides an optional terminating action for the repetitive inspections required by AD 2014–11–02. This AD retains the

requirements of AD 2014–11–02, provides an optional terminating action for the repetitive inspections, and reduces the applicability by excluding certain post-modified helicopters. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 17, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 17, 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 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. Service information that is incorporated by reference is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0195.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0195; 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 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: Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email matthew.fuller@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2014–11–02, Amendment 39–17852 (79 FR 33050, June 10, 2014) (AD 2014–11–02). AD 2014–11–02 applied to Airbus Helicopters (previously Eurocopter

France) Model SA-365N, SA-365N1, AS-365N2, and AS 365 N3 helicopters. The NPRM published in the **Federal Register** on April 22, 2021 (86 FR 21231). The NPRM proposed to continue to require, for helicopters that have a No. 9 frame that has had any repair or alteration made, within 10 hours time-in-service (TIS) after the effective date of the AD and at intervals not to exceed 110 hours TIS thereafter, inspecting the LH and RH frame No. 9 for a crack in the areas of the latch support and stretcher support with a 10X or higher power magnifying glass. For all other helicopters, the NPRM proposed to require the inspection within 110 hours TIS after the effective date of the AD and thereafter at intervals not to exceed 110 hours TIS. If there is a crack, the NPRM proposed to continue to require, before further flight, repairing the crack. The NPRM also proposed to provide an optional terminating action for the repetitive inspections that would consist of installing Eurocopter modification (MOD) 53C17 or MOD 53D02, or Airbus Helicopters MOD 07 53D21 or MOD 07 53D22, as applicable to your helicopter.

The NPRM was prompted by EASA AD 2012-0108R1, dated September 19, 2019 (EASA AD 2012-0108R1), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for certain Airbus Model helicopters except those that have been modified by Eurocopter MOD 53C17 or MOD 53D02, or Airbus Helicopters (AH) MOD 07 53D21 or MOD 07 53D22. EASA AD 2012-0108R1 revises EASA AD 2012-0108-E, dated June 15, 2012 (EASA AD 2012-0108-E), which was issued after a crack was discovered during the "T" inspection of an AS365 helicopter. The crack started at a rivet hole of a doubler that was installed on the frame No. 9 in accordance with Eurocopter Alert Service Bulletin No. 53.00.42, dated January 31, 2001. EASA stated in EASA AD 2012-0108-E that structural alteration of frame No. 9 by modifications or repairs can result in fatigue crack initiation under normal operational loads. According to EASA, this condition, if not corrected, could lead to crack propagation and failure of frame No. 9, which would adversely affect the structural integrity of the helicopter. For these reasons, EASA AD 2012-0108-E required repetitive inspections of frame No. 9 for a crack in the area of the doubler or any repair performed in the area of the latch support and stretcher support. EASA advises in EASA AD 2012-0108R1 that Airbus Helicopters developed MOD 07

53D21 and MOD 07 53D22. Consequently, EASA AD 2012-0108R1 was issued to introduce the MODs as optional terminating action for the repetitive inspections, reduce the applicability by excluding certain post-MOD helicopters, and make some editorial changes that do not affect the required actions.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM nor 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 1 CFR Part 51

Airbus Helicopters has co-published as one document Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 2, dated December 20, 2018 (EASB 05.00.63 Rev 2), for Model AS365-series helicopters and EASB No. 05.00.30, Revision 2, dated December 20, 2018 (EASB 05.00.30 Rev 2), for non-FAA type certificated Model AS565-series helicopters. EASB 05.00.63 Rev 2 is incorporated by reference in this AD; EASB 05.00.30 Rev 2 is not.

EASB 05.00.63 Rev 2 applies to helicopters with a frame No. 9 that has not been modified by MOD 07 53C17, 07 53D21, 07 53D22, or 07 53D02, and that has had doublers installed or repairs performed in accordance with certain service instructions. EASB 05.00.63 Rev 2 describes procedures for inspecting the frame No. 9 for a crack and specifies contacting Airbus Helicopters for further procedures if there is a crack.

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 reviewed Airbus Helicopters Service Bulletin SB No. AS365-53.00.57, Revision 0, dated December 20, 2018 (SB AS365-53.00.57), for

Model AS365-series helicopters. SB AS365-53.00.57 specifies replacing the upper section of the No. 9 frame with a reinforced version as an option to terminate the visual inspections specified in EASB 05.00.63 Rev 2.

The FAA also reviewed Eurocopter Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 1, dated June 18, 2012 (EASB 05.00.63 Rev 1). EASB 05.00.63 Rev 1 specifies the same procedures as EASB 05.00.63 Rev 2; however, EASB 05.00.63 Rev 2 excludes helicopters with certain MODs installed from its effectivity.

Differences Between This AD and the EASA AD

EASA AD 2012-0108R1 requires contacting Airbus Helicopters for repair instructions if there is a crack; this AD does not. EASA AD 2012-0108R1 applies to Airbus Helicopters Model 365-series helicopters with a frame No. 9 on which certain doublers or repairs have been accomplished; this AD applies to those model helicopters regardless of if those doublers or repairs have been accomplished.

Costs of Compliance

The FAA estimates that this AD affects 33 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this AD. At an average labor rate of \$85 per hour, inspecting the LH and RH frame No. 9 takes about 3 work-hours, for a cost per helicopter of \$255 and a total cost to U.S. operators of \$8,415 per inspection cycle. Repairing a cracked frame No. 9 takes about 20 work-hours, and required parts cost about \$15,000, for a cost per helicopter of \$16,700.

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:
 - a. Removing Airworthiness Directive (AD) 2014–11–02, Amendment 39–17852 (79 FR 33050, June 10, 2014); and
 - b. Adding the following new AD:

2021–13–19 Airbus Helicopters:

Amendment 39–21624; Docket No. FAA–2021–0195; Project Identifier MCAI–2020–00262–R.

(a) Applicability

This airworthiness directive (AD) applies to Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters, certificated in any category, except helicopters with Eurocopter modification (MOD) 53C17 or MOD 53D02, or Airbus Helicopters MOD 07 53D21 or MOD 07 53D22, installed.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in frame number (No.) 9, which if not detected and corrected, could result in failure of frame No. 9, loss of structural integrity, and subsequent loss of control of the helicopter.

(c) Affected ADs

This AD replaces AD 2014–11–02, Amendment 39–17852 (79 FR 33050, June 10, 2014).

(d) Effective Date

This AD is effective August 17, 2021.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) For helicopters that have any repair or alteration to the frame No. 9, within 10 hours time-in-service (TIS) after the effective date of this AD and thereafter at intervals not to exceed 110 hours TIS, using a 10X or higher power magnifying glass, inspect the left-hand (LH) and right-hand (RH) frame No. 9 for a crack in the area of the latch support and stretcher support, as depicted in Figure 1 of Airbus Helicopters Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 2, dated December 20, 2018 (EASB 05.00.63).

(2) For all other helicopters, within 110 hours TIS after the effective date of this AD and thereafter at intervals not to exceed 110 hours TIS, perform the inspection in paragraph (f)(1) of this AD.

(3) If there is a crack, before further flight, repair the frame No. 9. Repairing a frame is not terminating action for the repetitive inspections required by paragraphs (f)(1) and (2) of this AD.

(4) As an optional terminating action for the repetitive inspections required by paragraphs (f)(1) and (2) of this AD, replace the upper section of frame No. 9 with a reinforced frame, Eurocopter MOD 53C17 or MOD 53D02, or Airbus Helicopters MOD 07 53D21 or MOD 07 53D22.

(g) Special Flight Permits

Special flight permits to a repair facility may be issued provided that the flight does not exceed 10 hours TIS, any crack does not exceed a maximum crack length of 80 mm, and no passengers are onboard.

(h) Credit for Previous Actions

You may take credit for the actions required by paragraphs (f)(1) and (2) of this AD if you performed them before the effective date of this AD using Eurocopter Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 1, dated June 18, 2012.

(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 office, 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 Matthew Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email matthew.fuller@faa.gov.

(2) Eurocopter Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 1, dated June 18, 2012, which is not incorporated by reference, contains additional information about the subject of this AD. This service information is available at the contact information 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 2012–0108R1, dated September 19, 2019. You may view the EASA AD on the internet at <https://www.regulations.gov> in Docket No. FAA–2021–0195.

(k) Subject

Joint Aircraft Service Component (JASC) Code: 5300, Fuselage Structure.

(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) Airbus Helicopters Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 2, dated December 20, 2018.

(ii) [Reserved]

Note 1 to paragraph (l)(2)(ii): Airbus Helicopters Emergency Alert Service Bulletin EASB No. 05.00.63, Revision 2, dated December 20, 2018 is co-published as one document along with Airbus Helicopters Emergency Alert Service Bulletin EASB No. 05.00.30, Revision 2, dated December 20, 2018, which is not incorporated by reference in this AD.

(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/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: fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on June 17, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness
Division, Aircraft Certification Service.

[FR Doc. 2021-14777 Filed 7-12-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31377; Amdt. No. 3963]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 13, 2021. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 13, 2021.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, 8260-15B, when required by an entry on 8260-15A, and 8260-15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial

number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on June 25, 2021.

Wade E.K. Terrell,

Aviation Safety, Flight Standards Service, Manager (A), Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 12 August 2021

Fairbanks, AK, Fairbanks Intl, Takeoff Minimums and Obstacle DP, Amdt 6B
Groveland, CA, E45, RNAV (GPS) RWY 9, Orig-D
Vacaville, CA, KVCB, RNAV (GPS) RWY 20, Amdt 1B
Fort Lauderdale, FL, KFL, ILS OR LOC RWY 10R, Amdt 2
Fort Lauderdale, FL, KFL, ILS OR LOC RWY 28L, Amdt 2
Fort Lauderdale, FL, KFL, RNAV (GPS) RWY 10R, Amdt 2
Fort Lauderdale, FL, KFL, RNAV (GPS) RWY 28L, Amdt 2
West Palm Beach, FL, KPBI, ILS OR LOC RWY 10L, Amdt 28
West Palm Beach, FL, KPBI, RNAV (GPS) Y RWY 10L, Amdt 4
West Palm Beach, FL, KPBI, RNAV (RNP) Z RWY 10L, Amdt 2
West Palm Beach, FL, KPBI, RNAV (RNP) Z RWY 14, Amdt 1
West Palm Beach, FL, KPBI, RNAV (RNP) Z RWY 28R, Amdt 1
West Palm Beach, FL, KPBI, RNAV (RNP) Z RWY 32, Amdt 1
Ruston, LA, KRSN, RNAV (GPS) RWY 36, Amdt 1
Ruston, LA, Ruston Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
Ruston, LA, KRSN, VOR–A, Amdt 1
Houston, MO, M48, RNAV (GPS) RWY 34, Amdt 1
Morristown, NJ, KMMU, ILS OR LOC RWY 23, Amdt 13

Morristown, NJ, KMMU, RNAV (GPS) Z RWY 23, Amdt 3

[FR Doc. 2021–14815 Filed 7–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31378; Amdt. No. 3964]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 13, 2021. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 13, 2021.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in

the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on June 25, 2021.

Wade E.K. Terrell,

Aviation Safety, Flight Standards Service, Manager (A), Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, CFR part 97, is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

- 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * Effective Upon Publication

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12-Aug-21	OH	Georgetown	Brown County	0/2805	5/19/21	RNAV (GPS) RWY 36, Orig-B.
12-Aug-21	FL	Marathon	The Florida Keys Mara- thon Intl.	1/0513	6/16/21	NDB-A, Orig-A.
12-Aug-21	IA	Ames	Ames Muni	1/1030	6/10/21	VOR RWY 31, Amdt 10A.
12-Aug-21	NM	Raton	Raton Muni/Crews Fld ...	1/1073	5/7/21	RNAV (GPS) RWY 25, Orig-B.
12-Aug-21	IA	Ames	Ames Muni	1/1234	6/10/21	RNAV (GPS) RWY 1, Amdt 2A.
12-Aug-21	AK	Anchorage	Merrill Fld	1/1307	5/12/21	RNAV (GPS)—A, Amdt 1A.
12-Aug-21	CA	San Luis Obispo	San Luis County Rgnl ...	1/1311	5/12/21	LOC RWY 11, Orig-B.
12-Aug-21	CA	San Luis Obispo	San Luis County Rgnl ...	1/1314	5/12/21	VOR OR TACAN-A, Amdt 6B.
12-Aug-21	NE	Lincoln	Lincoln	1/1619	6/15/21	RNAV (GPS) RWY 14, Amdt 1A.
12-Aug-21	NE	Lincoln	Lincoln	1/1621	6/15/21	RNAV (GPS) RWY 18, Amdt 1B.
12-Aug-21	NE	Lincoln	Lincoln	1/1623	6/15/21	RNAV (GPS) RWY 36, Amdt 1C.
12-Aug-21	NE	Lincoln	Lincoln	1/1625	6/15/21	VOR RWY 17, Amdt 7.
12-Aug-21	NE	Lincoln	Lincoln	1/1627	6/15/21	RNAV (GPS) RWY 32, Orig-A.
12-Aug-21	CA	Petaluma	Petaluma Muni	1/1639	4/23/21	RNAV (GPS) RWY 29, Orig-B.
12-Aug-21	TN	Athens	Mcminn County	1/1863	4/23/21	RNAV (GPS) RWY 20, Amdt 1B.
12-Aug-21	TN	Athens	Mcminn County	1/1864	4/23/21	RNAV (GPS) RWY 2, Orig-B.
12-Aug-21	NM	Roswell	Roswell Air Center	1/2188	4/14/21	RNAV (GPS) RWY 21, Orig-A.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2585	6/15/21	ILS OR LOC RWY 25, Amdt 7D.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2586	6/15/21	RNAV (GPS) RWY 23, Amdt 1.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2587	6/15/21	RNAV (GPS) RWY 25, Amdt 1.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2589	6/15/21	RNAV (GPS) RWY 5, Amdt 1.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2591	6/15/21	RNAV (GPS) RWY 7, Amdt 2.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2593	6/15/21	VOR/DME RWY 5, Orig.
12-Aug-21	NM	Farmington	Four Corners Rgnl	1/2594	6/15/21	VOR/DME RWY 7, Amdt 4A.
12-Aug-21	NC	Lumberton	Lumberton Rgnl	1/2623	6/16/21	ILS OR LOC RWY 5, Amdt 1C.
12-Aug-21	NC	Lumberton	Lumberton Rgnl	1/2624	6/16/21	RNAV (GPS) RWY 13, Orig-B.
12-Aug-21	NC	Lumberton	Lumberton Rgnl	1/2626	6/16/21	RNAV (GPS) RWY 23, Orig-B.
12-Aug-21	NC	Lumberton	Lumberton Rgnl	1/2628	6/16/21	RNAV (GPS) RWY 5, Orig-B.
12-Aug-21	NC	Washington	Washington-Warren	1/2648	6/16/21	LOC RWY 5, Amdt 1C.
12-Aug-21	NC	Washington	Washington-Warren	1/2649	6/16/21	RNAV (GPS) RWY 35, Amdt 1A.
12-Aug-21	NC	Washington	Washington-Warren	1/2651	6/16/21	RNAV (GPS) RWY 23, Amdt 1A.
12-Aug-21	NC	Washington	Washington-Warren	1/2652	6/16/21	RNAV (GPS) RWY 5, Amdt 1B.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12-Aug-21	NY	Farmingdale	Republic	1/2683	6/10/21	ILS OR LOC RWY 14, Amdt 8E.
12-Aug-21	TX	Big Spring	Big Spring Mc Mahon-Wrinkle.	1/2902	3/22/21	RNAV (GPS) RWY 6, Orig-B.
12-Aug-21	IL	Pekin	Pekin Muni	1/3113	6/17/21	RNAV (GPS) RWY 9, Orig-A.
12-Aug-21	IL	Pekin	Pekin Muni	1/3114	6/17/21	RNAV (GPS) RWY 27, Orig-A.
12-Aug-21	IL	Pekin	Pekin Muni	1/3115	6/17/21	VOR-A, Amdt 7A.
12-Aug-21	AK	Valdez	Valdez Pioneer Fld	1/3168	5/17/21	LDA-H, Amdt 2B.
12-Aug-21	SC	Moncks Corner	Berkeley County	1/3246	5/27/21	VOR/DME-A, Orig-A.
12-Aug-21	OH	Dayton	Greene County-Lewis A Jackson Rgnl.	1/3479	3/22/21	RNAV (GPS) RWY 25, Amdt 1.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3746	6/10/21	ILS OR LOC RWY 1, Amdt 38A.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3747	6/10/21	ILS OR LOC RWY 19, Amdt 8A.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3748	6/10/21	ILS OR LOC RWY 23, Amdt 11B.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3749	6/10/21	ILS OR LOC RWY 5, Orig-B.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3750	6/10/21	RNAV (GPS) RWY 1, Orig-A.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3751	6/10/21	RNAV (GPS) RWY 19, Orig-A.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3754	6/10/21	RNAV (GPS) RWY 23, Orig-B.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3755	6/10/21	RNAV (GPS) RWY 5, Orig-B.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3756	6/10/21	VOR RWY 23, Amdt 10.
12-Aug-21	OH	Akron	Akron-Canton Rgnl	1/3757	6/10/21	VOR RWY 5, Amdt 3A.
12-Aug-21	NY	Farmingdale	Republic	1/3942	6/10/21	RNAV (GPS) Y RWY 14, Amdt 2D.
12-Aug-21	CA	Santa Ynez	Santa Ynez	1/3984	4/23/21	GPS-A, Orig-C.
12-Aug-21	PA	Pottstown	Pottstown Muni	1/4096	6/16/21	RNAV (GPS) RWY 26, Orig-A.
12-Aug-21	PA	Pottstown	Pottstown Muni	1/4097	6/16/21	VOR-B, Amdt 5A.
12-Aug-21	NE	Hartington	Hartington Muni/Bud Becker Fld.	1/4168	3/22/21	RNAV (GPS) RWY 31, Orig-D.
12-Aug-21	MO	Neosho	Neosho Hugh Robinson	1/4417	6/8/21	RNAV (GPS) RWY 1, Amdt 1A.
12-Aug-21	MO	Neosho	Neosho Hugh Robinson	1/4418	6/8/21	RNAV (GPS) RWY 19, Amdt 1A.
12-Aug-21	IA	Rock Rapids	Rock Rapids Muni	1/4659	3/22/21	RNAV (GPS) RWY 34, Amdt 1.
12-Aug-21	SC	Moncks Corner	Berkeley County	1/4803	5/27/21	RNAV (GPS) RWY 5, Orig.
12-Aug-21	SC	Moncks Corner	Berkeley County	1/4824	5/27/21	RNAV (GPS) RWY 23, Orig-A.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4910	6/10/21	ILS OR LOC RWY 9, Amdt 18A.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4911	6/10/21	ILS OR LOC RWY 18L, Amdt 7B.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4912	6/10/21	ILS OR LOC RWY 18R, Amdt 1B.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4913	6/10/21	ILS OR LOC RWY 36C, Amdt 41C.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4914	6/10/21	ILS OR LOC RWY 36L, Amdt 1B.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4915	6/10/21	ILS OR LOC RWY 36R, Amdt 8B.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4916	6/10/21	RNAV (GPS) Y RWY 9, Amdt 1A.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4917	6/10/21	RNAV (GPS) Y RWY 18C, Amdt 1C.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4918	6/10/21	RNAV (GPS) Y RWY 18L, Amdt 1C.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4919	6/10/21	RNAV (GPS) Y RWY 18R, Amdt 1C.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4920	6/10/21	RNAV (GPS) Y RWY 27, Orig-B.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4922	6/10/21	RNAV (GPS) Y RWY 36C, Amdt 1C.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4926	6/10/21	RNAV (GPS) Y RWY 36L, Amdt 1C.
12-Aug-21	KY	Covington	Cincinnati/Northern Kentucky Intl.	1/4927	6/10/21	RNAV (GPS) Y RWY 36R, Amdt 1C.
12-Aug-21	CA	Mammoth Lakes	Mammoth Yosemite	1/5194	6/11/21	RNAV (GPS) RWY 27, Amdt 1.
12-Aug-21	ND	Williston	Williston Basin Intl	1/5215	6/21/21	RNAV (GPS) RWY 4, Orig.
12-Aug-21	WI	Green Bay	Green Bay-Austin Straubel Intl.	1/5508	4/27/21	ILS OR LOC RWY 6, Amdt 21D.
12-Aug-21	WI	Green Bay	Green Bay-Austin Straubel Intl.	1/5509	4/27/21	RNAV (GPS) RWY 24, Amdt 1A.
12-Aug-21	WI	Green Bay	Green Bay-Austin Straubel Intl.	1/5510	4/27/21	VOR-A, Orig-B.
12-Aug-21	WI	Green Bay	Green Bay-Austin Straubel Intl.	1/5511	4/27/21	LOC BC RWY 24, Amdt 19C.
12-Aug-21	WI	Green Bay	Green Bay-Austin Straubel Intl.	1/5514	4/27/21	ILS OR LOC RWY 36, Amdt 9A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12-Aug-21	IL	Marion	Veterans Airport Of Southern Illinois.	1/5757	6/18/21	RNAV (GPS) RWY 20, Amdt 1D.
12-Aug-21	IL	Marion	Veterans Airport Of Southern Illinois.	1/5759	6/18/21	RNAV (GPS) RWY 2, Amdt 1D.
12-Aug-21	IL	Marion	Veterans Airport Of Southern Illinois.	1/5760	6/18/21	ILS OR LOC RWY 20, Amdt 12C.
12-Aug-21	IL	Pontiac	Pontiac Muni	1/5897	6/3/21	VOR RWY 24, Amdt 2.
12-Aug-21	IL	Pontiac	Pontiac Muni	1/5898	6/3/21	RNAV (GPS) RWY 24, Orig.
12-Aug-21	IL	Pontiac	Pontiac Muni	1/5899	6/3/21	RNAV (GPS) RWY 6, Orig-A.
12-Aug-21	GA	Dalton	Dalton Muni	1/5940	5/17/21	RNAV (GPS) RWY 32, Amdt 1.
12-Aug-21	MN	St James	St James Muni	1/6101	6/8/21	RNAV (GPS) RWY 15, Amdt 1A.
12-Aug-21	MN	St James	St James Muni	1/6102	6/8/21	RNAV (GPS) RWY 33, Amdt 1A.
12-Aug-21	KY	Somerset	Lake Cumberland Rgnl	1/6193	4/15/21	Takeoff Minimum and Obstacle DP, Amdt 4.
12-Aug-21	NY	Rome	Griffiss Intl	1/6391	5/17/21	RNAV (GPS) RWY 15, Amdt 1B.
12-Aug-21	NY	Rome	Griffiss Intl	1/6403	5/17/21	RNAV (GPS) RWY 33, Amdt 2A.
12-Aug-21	MO	Kaiser/Lake Ozark	Lee C Fine Meml	1/6407	6/8/21	LOC/DME RWY 22, Amdt 2A.
12-Aug-21	MO	Kaiser/Lake Ozark	Lee C Fine Meml	1/6410	6/8/21	RNAV (GPS) RWY 22, Amdt 1A.
12-Aug-21	MO	Kaiser/Lake Ozark	Lee C Fine Meml	1/6413	6/8/21	VOR RWY 4, Amdt 7B.
12-Aug-21	WI	Platteville	Platteville Muni	1/6737	4/29/21	RNAV (GPS) RWY 33, Orig.
12-Aug-21	WI	Platteville	Platteville Muni	1/6740	4/29/21	RNAV (GPS) RWY 25, Orig-A.
12-Aug-21	WI	Platteville	Platteville Muni	1/6741	4/29/21	RNAV (GPS) RWY 15, Orig.
12-Aug-21	WI	Platteville	Platteville Muni	1/6742	4/29/21	RNAV (GPS) RWY 7, Orig-C.
12-Aug-21	TX	Center	Center Muni	1/6845	4/8/21	NDB RWY 17, Amdt 2B.
12-Aug-21	TX	Center	Center Muni	1/6846	4/8/21	RNAV (GPS) RWY 35, Orig-C.
12-Aug-21	TX	Center	Center Muni	1/6847	4/8/21	RNAV (GPS) RWY 17, Orig-D.
12-Aug-21	MS	Indianola	Indianola Muni	1/6879	4/16/21	RNAV (GPS) RWY 18, Amdt 2A.
12-Aug-21	MS	Indianola	Indianola Muni	1/6880	4/16/21	RNAV (GPS) RWY 36, Amdt 2A.
12-Aug-21	MS	Indianola	Indianola Muni	1/6881	4/16/21	VOR/DME-A, Amdt 9C.
12-Aug-21	MS	Indianola	Indianola Muni	1/6882	4/16/21	VOR/DME-B, Amdt 5C.
12-Aug-21	AL	Bessemer	Bessemer	1/6883	4/16/21	ILS OR LOC RWY 5, Amdt 2A.
12-Aug-21	AL	Bessemer	Bessemer	1/6884	4/16/21	RNAV (GPS) RWY 23, Orig-A.
12-Aug-21	AL	Bessemer	Bessemer	1/6885	4/16/21	RNAV (GPS) RWY 5, Amdt 1A.
12-Aug-21	AL	Bessemer	Bessemer	1/6886	4/16/21	VOR RWY 5, Amdt 6A.
12-Aug-21	UT	Manti	Manti-Ephraim	1/7075	4/9/21	RNAV (GPS) RWY 3, Orig-A.
12-Aug-21	FL	Marathon	The Florida Keys Marathon Intl.	1/7151	6/16/21	RNAV (GPS) RWY 25, Amdt 1A.
12-Aug-21	GA	Columbus	Columbus	1/7153	6/4/21	ILS OR LOC RWY 6, Amdt 25C.
12-Aug-21	GA	Columbus	Columbus	1/7154	6/4/21	VOR-A, Amdt 23B.
12-Aug-21	GA	Columbus	Columbus	1/7156	6/4/21	RNAV (GPS) RWY 24, Orig-C.
12-Aug-21	GA	Columbus	Columbus	1/7157	6/4/21	RNAV (GPS) RWY 13, Orig-C.
12-Aug-21	GA	Columbus	Columbus	1/7159	6/4/21	RNAV (GPS) RWY 6, Orig-B.
12-Aug-21	NC	Winston Salem	Smith Reynolds	1/7160	6/4/21	RNAV (GPS) RWY 33, Orig-D.
12-Aug-21	MN	Faribault	Faribault Muni-Liz Wall Strohfus Fld.	1/7287	6/8/21	VOR-A, Amdt 6B.
12-Aug-21	TX	Andrews	Andrews County	1/7579	6/22/21	RNAV (GPS) RWY 16, Orig-A.
12-Aug-21	TX	Carthage	Panola County-Sharpe Fld.	1/7656	6/10/21	NDB RWY 35, Amdt 2A.
12-Aug-21	MN	Ada/Twin Valley	Norman County Ada/Twin Valley.	1/7887	6/23/21	RNAV (GPS) RWY 33, Orig-B.
12-Aug-21	CT	Chester	Chester	1/8008	5/27/21	RNAV (GPS) RWY 17, Orig-A.
12-Aug-21	CT	Chester	Chester	1/8009	5/27/21	RNAV (GPS) RWY 35, Orig-A.
12-Aug-21	IL	Chicago/Lake In The Hills.	Lake In The Hills	1/8225	6/8/21	VOR RWY 26, Amdt 4A.
12-Aug-21	HI	Lanai City	Lanai	1/8227	6/15/21	ILS OR LOC RWY 3, Amdt 1B.
12-Aug-21	HI	Lanai City	Lanai	1/8228	6/15/21	RNAV (GPS) RWY 3, Orig-C.
12-Aug-21	HI	Lanai City	Lanai	1/8229	6/15/21	VOR OR TACAN RWY 3, Amdt 7B.
12-Aug-21	HI	Lanai City	Lanai	1/8231	6/15/21	VOR OR TACAN OR GPS-A, Amdt 8A.
12-Aug-21	GA	Blakely	Early County	1/8232	6/8/21	RNAV (GPS) RWY 5, Amdt 2A.
12-Aug-21	GA	Blakely	Early County	1/8233	6/8/21	RNAV (GPS) RWY 23, Amdt 2A.
12-Aug-21	AL	Cullman	Cullman Rgnl-Folsom Fld.	1/8345	5/4/21	RNAV (GPS) RWY 20, Amdt 1B.
12-Aug-21	NM	Alamogordo	Alamogordo-White Sands Rgnl.	1/8470	6/23/21	RNAV (GPS) RWY 4, Amdt 2A.
12-Aug-21	MI	Allegan	Padgham Fld	1/8550	6/8/21	RNAV (GPS) RWY 11, Orig-B.
12-Aug-21	MI	Allegan	Padgham Fld	1/8551	6/8/21	RNAV (GPS) RWY 29, Orig-A.
12-Aug-21	TX	Longview	East Texas Rgnl	1/8556	6/8/21	VOR/DME OR TACAN RWY 31, Amdt 7A.
12-Aug-21	AZ	Page	Page Muni	1/8787	6/15/21	RNAV (GPS) RWY 15, Orig.
12-Aug-21	AZ	Page	Page Muni	1/8788	6/15/21	RNAV (GPS) RWY 33, Orig.
12-Aug-21	AZ	Page	Page Muni	1/8789	6/15/21	VOR-B, Orig-A.
12-Aug-21	AL	Courtland	Courtland	1/9204	6/10/21	RNAV (GPS) RWY 13, Amdt 2A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12-Aug-21	AL	Courtland	Courtland	1/9205	6/10/21	RNAV (GPS) RWY 31, Amdt 2A.
12-Aug-21	CA	Imperial	Imperial County	1/9434	5/27/21	VOR OR GPS-A, Amdt 4A.
12-Aug-21	LA	Welsh	Welsh	1/9528	5/25/21	VOR/DME OR GPS RWY 7, Amdt 3B.
12-Aug-21	IN	Portland	Portland Muni	1/9605	5/25/21	RNAV (GPS) RWY 9, Amdt 1A.
12-Aug-21	IN	Portland	Portland Muni	1/9609	5/25/21	RNAV (GPS) RWY 27, Amdt 1A.
12-Aug-21	TN	Rockwood	Rockwood Muni	1/9634	6/10/21	VOR/DME RWY 22, Amdt 6B.
12-Aug-21	TN	Rockwood	Rockwood Muni	1/9635	6/10/21	RNAV (GPS) RWY 22, Amdt 1A.
12-Aug-21	TN	Rockwood	Rockwood Muni	1/9636	6/10/21	RNAV (GPS) RWY 4, Orig-A.
12-Aug-21	QM	Midway Atoll	Henderson Fld	1/9729	5/28/21	RNAV (GPS) RWY 24, Orig-D.
12-Aug-21	QM	Midway Atoll	Henderson Fld	1/9730	5/28/21	RNAV (GPS) RWY 6, Orig-D.
12-Aug-21	QM	Midway Atoll	Henderson Fld	1/9731	5/28/21	NDB RWY 6, Orig-C.
12-Aug-21	QM	Midway Atoll	Henderson Fld	1/9732	5/28/21	NDB RWY 24, Orig-C.
12-Aug-21	AK	Cordova	Merle K (Mudhole) Smith.	1/9877	5/7/21	ILS OR LOC RWY 27, Amdt 11C.
12-Aug-21	AK	Cordova	Merle K (Mudhole) Smith.	1/9878	5/7/21	RNAV (GPS) RWY 27, Amdt 2A.
12-Aug-21	AK	Cordova	Merle K (Mudhole) Smith.	1/9879	5/7/21	RNAV (GPS)-B, Amdt 2.
12-Aug-21	AK	Atka	Atka	1/9894	5/12/21	RNAV (GPS)-A, Orig-A.
12-Aug-21	NM	Portales	Portales Muni	1/9903	5/7/21	RNAV (GPS) RWY 1, Orig.
12-Aug-21	IA	Sac City	Sac City Muni	1/9955	5/21/21	RNAV (GPS) RWY 18, Orig-A.

[FR Doc. 2021-14816 Filed 7-12-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0247]

RIN 1625-AA00

Safety Zone; Cumberland River, Nashville, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone from mile marker 191.1 to 191.5 of the Cumberland River. This action is necessary to provide for the safety of life on these navigable waters near Korean Veterans Bridge, Nashville, TN, during Music City Grand Prix on August 6 through August 8, 2021. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 2 p.m. on August 6, 2021 until 7 p.m. on August 8, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0247 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 about this proposed rulemaking, call or email Petty Officer Third Class Benjamin Gardner and Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615-736-5421, email Benjamin.t.gardner@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 it is impracticable. The Coast Guard was notified of the event without ample time for the NPRM process. We must establish this regulation by August 6, 2021 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists

for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to ensure the safety of the participants and vessels during the Music City Grand Prix Indy Car Race starting on August 6, 2021.

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 Sector Ohio Valley (COTP) has determined that potential hazards associated with the Music City Grand Prix from August 6, 2021 until August 8, 2021, will be a safety concern for anyone within a 0.4 mile radius of the Korean Veterans Bridge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the Music City Grand Prix is occurring.

IV. Discussion of the Rule

The COTP is establishing a safety zone on the following dates during these time periods: From 2 p.m. to 6:30 p.m. on August 6, 2021; from noon to 5 p.m. on August 7, 2021; and from 4:30 p.m. to 7 p.m. on August 8, 2021. The safety zone would cover all navigable waters between mile marker 191.1 and 191.5 on the Cumberland River in Nashville, TN. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled Music City Grand Prix. No vessel or person would 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, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Cumberland River before or after the time of the events on each day. Moreover, the Coast Guard would 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 proposed rule involves a safety zone lasting 12 hours spread over the course of 3 days that would prohibit entry within .4 miles of the Korean Veterans Bridge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 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 protestors. 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 is amending 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. 0170.1.

- 2. Add § 165.T08–0247 to read as follows:

§ 165.T08–0247 Safety Zone; Cumberland River, Nashville, TN.

(a) *Location.* The following area is a safety zone: All navigable waters of the

Cumberland River from mile marker 191.1 to mile marker 191.5.

(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 Sector Ohio Valley (COTP) in the enforcement of the safety zone.

(c) *Regulations*. (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF-FM radio channel 16 or phone at 1-800-253-7465. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement periods*. This rule will be enforced from 2 p.m. until 6:30 p.m. on August 6, 2021, from noon until 5 p.m. on August 7, 2021, and from 4:30 p.m. until 7 p.m. on August 8, 2021.

Dated: July 1, 2021.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2021-14644 Filed 7-12-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

RIN 1810-AB63

American Rescue Plan Act Emergency Assistance to Non-Public Schools Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final requirements.

SUMMARY: The U.S. Department of Education (Department) establishes requirements for the American Rescue Plan Emergency Assistance to Non-Public Schools (ARP EANS) program under the American Rescue Plan Act of 2021 (ARP Act). This document is intended to clarify the requirements applicable to the ARP EANS program, including the requirement to provide services or assistance to non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the novel Coronavirus Disease 2019 (COVID-19) emergency.

DATES: These final requirements are effective July 13, 2021.

FOR FURTHER INFORMATION CONTACT: Britt Jung, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Email: EANS@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: Section 2002 of the ARP Act, titled "Emergency Assistance to Non-Public Schools," appropriates \$2,750,000,000 for the Department to make allocations to Governors under the ARP EANS program "to provide services or assistance to non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency."¹

Program Authority: ARP Act, Public Law 117-2, March 11, 2021.

Background: The ARP Act extends the EANS program authorized under section 312(d) of division M of the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSA Act), with two exceptions: (1) A State educational agency (SEA) may only provide services or assistance under ARP EANS to non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the COVID-19 emergency, and (2) an SEA may not use ARP EANS funds to provide reimbursements to any non-public school.

Under the ARP EANS program, consistent with section 312(d)(1) of division M of the CRRSA Act, the Department will allot funds by formula to each Governor with an approved application based on the State's relative share of children aged 5 through 17 who are from families at or below 185 percent of the 2020 Federal poverty level and enrolled in non-public schools, as determined by the Department on the basis of non-public school enrollment data from the U.S. Census Bureau's American Community Survey (ACS) Public Use Microdata Sample (PUMS) for 2015-2019, which can be accessed here: <https://www.census.gov/programs-surveys/acs/microdata.html>. The amount available

¹ Under these final requirements, "students from low-income families" has the same meaning as "low-income students" under section 2002(a) of the ARP Act. "Students from low-income families" is a term used in section 312(d) of division M of the Coronavirus Response and Relief Supplemental Appropriations Act, 2021.

to each State may be found at: <https://oese.ed.gov/offices/education-stabilization-fund/emergency-assistance-non-public-schools/>.

As described in more detail below, the Secretary of Education (Secretary) is establishing final requirements for the ARP EANS program to (1) make clear that, with the exceptions noted above, the requirements of the EANS program authorized under section 312(d) of division M of the CRRSA Act (CRRSA EANS) apply to ARP EANS, and (2) establish guidelines to determine that a non-public school enrolls a significant percentage of students from low-income families and is most impacted by the COVID-19 emergency.

Prior to issuing these final requirements, the Department invited comment regarding implementation of the requirement "to provide services or assistance to non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency" as part of the *Notice Inviting Applications and Announcing Allocations for the Emergency Assistance to Non-Public Schools Program Under the American Rescue Plan Act of 2021*, issued on April 12, 2021.² The Department received 66 comments, which it reviewed and considered in developing these final requirements.

With respect to the significant poverty percentage, comments generally fell into three groups that advocated for: (1) Establishing a specific significant poverty percentage, as high as 75 percent; (2) prioritizing schools in the same manner as under the CRRSA EANS program; or (3) providing a State discretion to determine the significant poverty percentage for non-public schools within the State. Commenters advocating for a specific high poverty percentage did so on the premise that it would ensure that resources are targeted to the most under-resourced communities, which they assert is consistent with congressional intent. Multiple commenters noted that a 75-percent poverty percentage would align with the definition of a "high-poverty school" used by the National Center for Education Statistics and the threshold for serving public schools in rank order, without regard to grade spans, applicable to within-district allocations under title I, part A (title I) of the Elementary and Secondary Education Act of 1965 (ESEA) (see section 1113(a)(3)(A) of the ESEA). By contrast, other commenters asserted that an

² <https://oese.ed.gov/files/2021/04/FINAL-ARP-EANS-notice-4.12.21.pdf>.

excessively rigorous, one-size-fits-all threshold would be inappropriate in the context of non-public schools and their States' specific circumstances and therefore recommended that States be given discretion to determine what constitutes a significant poverty percentage. In support of a more flexible approach, one State provided data indicating that a significant number of non-public schools that applied under CRRSA EANS would be ineligible under ARP EANS even with a poverty percentage as low as 30 percent. Taking these comments into account, the Department sought to establish a specific significant poverty percentage while also recognizing that there are State circumstances that may warrant a different significant poverty percentage in a given State.

In terms of determining the non-public schools most impacted by the COVID-19 emergency, commenters generally noted that the Department's *Frequently Asked Questions: Emergency Assistance to Non-Public Schools (EANS) Program as Authorized by the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSA Act)* (EANS FAQs)³ provided an appropriate range of factors. The final requirements include a majority of the factors identified in the Department's previously issued EANS FAQs.

General Requirements

Applicability of CRRSA EANS Requirements

Statute: Section 2002(a) of the ARP Act appropriates an additional \$2,750,000,000 for making allocations to Governors under the EANS program to provide services or assistance to non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the COVID-19 emergency. Section 2002(b) further clarifies that the funds provided under section 2002(a) may not be used to provide reimbursements to any non-public school.

Final Requirements: These requirements make clear that all of the provisions of the CRRSA EANS program also apply to the ARP EANS program with two exceptions: (1) An SEA may provide services or assistance under ARP EANS only to an eligible non-public school that enrolls a significant percentage of students from low-income families and is most impacted by the COVID-19 emergency, and (2) an SEA may not use ARP EANS funds to

provide reimbursements to a non-public school.

Reasons: The final requirements clarify for States that, except for the two exceptions noted in the statute, all of the requirements in the CRRSA EANS program apply to ARP EANS funds. Making this clarification ensures that States and non-public schools are aware of all EANS program requirements, including statutory timelines, assurances required in a Governor's application, and other application requirements for both the Governor's and a non-public school's application. The final requirements also clarify the allowable services and activities that an SEA may provide to non-public schools. Significantly, they make clear that, unlike under CRRSA EANS, an SEA may not use ARP EANS funds to provide reimbursements to any non-public school.

Determining Non-Public Schools To Be Served

Determining Non-Public Schools That May Receive Services or Assistance

Statute: Under section 2002(a) of the ARP Act, services or assistance to non-public schools under the ARP EANS program are limited to "non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency."

Final Requirements: The final requirements require a Governor, in his or her application for ARP EANS funds, to identify the significant poverty percentage and the factors of COVID-19 impact the State will use, after approval by the Secretary, to determine which non-public schools are eligible to receive services or assistance. In addition to meeting the definition of a non-public school in section 316(6) of division M of the CRRSA Act and the eligibility requirement in section 312(d)(9) of division M of the CRRSA Act, a non-public school must meet or exceed the State's significant poverty percentage and be most impacted by the COVID-19 emergency.

Reasons: This requirement clarifies those non-public schools that are eligible to receive services or assistance under the ARP EANS program. A non-public school must meet the definition of "non-public school" in section 316(6) of division M of the CRRSA Act and the eligibility requirement in section 312(d)(9) of division M of the CRRSA Act. In addition, the percentage of students from low-income families in the non-public school must meet or exceed either 40 percent or the State's approved alternate significant poverty

percentage. Finally, the non-public school must be most impacted by the COVID-19 emergency based on the State's factor(s).

The final requirements reflect nearly all the comments we received. They establish a specific significant poverty percentage that a State may adopt without further explanation, although that percentage is not as high as some commenters recommended for reasons discussed below. They also afford a State some discretion to propose an alternate significant poverty percentage based on circumstances within the State, as most commenters suggested. The final requirements do not, however, adopt the view of some commenters who suggested implementing ARP EANS in the same manner as CRRSA EANS to reduce burden on SEAs and non-public schools. We believe the ARP Act does not support this suggestion, because it specifically changed the language in the CRRSA Act from "prioritize services or assistance to non-public schools that enroll low-income students and are most impacted by the [COVID-19] emergency" to "provide services or assistance to non-public schools that enroll a significant percentage of low-income students and are most impacted by the [COVID-19] emergency." The ARP Act language differs from the CRRSA Act in two significant respects: (1) Rather than establishing a "priority" for serving schools with students from low-income families that then permits other non-public schools to be served, the ARP Act requires a non-public school to enroll a percentage of students from low-income families, and (2) the ARP Act requires that poverty percentage to be "significant." The final requirements reflect this change.

Enrollment of a Significant Percentage of Students From Low-Income Families

Statute: Under section 2002(a) of the ARP Act, services or assistance to non-public schools under the ARP EANS program is limited to "non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency."

Final Requirements: Under the final requirements, a non-public school is considered to enroll a significant percentage of students from low-income families, as defined in these requirements, if the percentage of students from low-income families enrolled in the school meets or exceeds 40 percent, based on the data source(s) selected by the State under these requirements. Alternatively, a State may propose and, if approved by the

³ <https://oese.ed.gov/files/2021/03/Final-EANS-FAQ-2.0-3.19.21.pdf>.

Secretary, use an alternate significant poverty percentage based on circumstances in the State, which may be (1) the State's average percentage of students from low-income families in public and non-public schools, (2) the average percentage of students from low-income families in non-public schools in the State that, for example, applied for or participated in the CRRSA EANS program, or (3) other factors that the State demonstrates support an alternate significant poverty percentage.

Reasons: A 40-percent poverty percentage has long been recognized as a measure of significant poverty to operate a schoolwide program under title I of the ESEA. In the context of title I, 40-percent poverty is the statutory threshold for a title I school to use title I funds to upgrade the entire educational program of a school and serve all students. (See section 1114(a)(1)(A) of the ESEA). Given Congress' recognition of 40 percent as significant within the context of title I, we believe it presents a reasonable threshold with respect to the ARP EANS program as well.

We recognize, however, that there may be circumstances in the State that may warrant establishing a different significant percentage of students from low-income families for non-public schools. As a result, under the final requirements, a State has the option of using an alternate significant poverty percentage upon approval by the Secretary based on factors in the State. To receive approval, a State must provide data and a supporting rationale to justify the use of such alternative as part of its ARP EANS application.

The final requirements permit a State to apply to use an alternate significant poverty percentage based on the State's average percentage of students from low-income families in both public and private schools. This option recognizes that the determination of what constitutes a significant poverty percentage may vary from State to State based on a particular State's relative level of poverty.

The final requirements also allow a State to apply to use an alternate significant poverty percentage based on, for example, the average percentage of students from low-income families in non-public schools in the State that applied for or participated in the CRRSA EANS program. Using an average percentage of poverty in non-public schools could allow a State to establish an appropriate significant poverty percentage relative to non-public schools in the State.

Finally, the final requirements also permit a State to support an alternate significant poverty percentage based on factors that the State demonstrates reflect significant poverty. For example, a State might submit data showing the relative rates of poverty in non-public schools as compared to public schools, or the percentage of non-public schools that would be excluded at different poverty percentages, and explain why those data support the requested alternate percentage.

We believe these alternatives address some commenters' concerns that a State should have the opportunity to propose a significant poverty percentage that reflects circumstances within the State. We know that poverty percentages vary considerably among States and between public and non-public schools. The alternatives permit a State to propose a significant poverty percentage relative to poverty within the State.

Most Impacted by the COVID-19 Emergency Statute

Under section 2002(a) of the ARP Act, services or assistance to non-public schools under the ARP EANS program is limited to "non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency."

Final Requirements: Under the final requirements, an SEA determines if a non-public school is most impacted by the COVID-19 emergency based on one or more of the following factors: (1) The number of COVID-19 infections per capita in the community or communities served by the non-public school; (2) the number of COVID-19 deaths per capita in the community or communities served by the non-public school; (3) data on the academic impact of lost instructional time and the social, emotional, or mental health impacts attributable to the disruption of instruction caused by the COVID-19 emergency; or (4) the economic impact of the COVID-19 emergency on the community or communities served by the non-public school. In addition to using one or more of these factors, an SEA may use other factors included in the State's approved application to determine which non-public schools are most impacted by the COVID-19 emergency.

Reasons: The final requirements afford a State several options from which to choose in assessing impact. COVID-19 infection and death rates are readily available⁴ and provide a

reasonable way to identify communities most impacted by the COVID-19 emergency. Additionally, students are facing significant academic challenges as a result of the lost instructional time,⁵ and social, emotional, and mental health impacts attributable to the disruption of instruction caused by the COVID-19 emergency. Depending upon the specific circumstances, these issues may be more pronounced in some non-public schools than others. Finally, the COVID-19 emergency has had a disproportionate economic impact on many communities,⁶ including high rates of unemployment, which may have a concomitant impact on non-public schools serving such communities.

Given the wide-ranging impact of the COVID-19 emergency on schools and communities throughout the Nation, we recognize that there is no single factor with which to assess the impact of the COVID-19 emergency on non-public schools. Thus, in addition to one or more of the above factors, the final requirements allow an SEA to use other factors included in the State's approved application to determine the non-public schools most impacted by the COVID-19 emergency.

We recognize that non-public schools often draw students from communities other than the one in which they are located. Thus, the factors in the final requirements related to per capita COVID-19 infections and deaths as well as economic impact are relative to the community or communities served by a non-public school, which the SEA has flexibility to determine.

The final requirements reflect many of the comments recommending that the Department use the factors in the EANS FAQs and give States a range of options. Some commenters urged that the impact of the COVID-19 emergency not be allowed to outweigh poverty. The final requirements use a majority of the factors in the EANS FAQs and permit an SEA to add others included in the State's approved application for EANS funding. They also make clear that a non-public school must meet both the

available at <https://covid.cdc.gov/covid-data-tracker/>, which includes community data on reported COVID-19 cases and deaths.

⁵ We note that section 312(d)(4)(L) of division M of the CRRSA Act specifically authorizes the use of EANS funds to address "learning loss," which the final requirements refer to as the "academic impact of lost instructional time."

⁶ See, e.g., Aaron Klein & Ember Smith, *Explaining the Economic Impact of COVID-19: Core Industries and the Hispanic Workforce*, Brookings Institution (Feb. 5, 2021), <https://www.brookings.edu/research/explaining-the-economic-impact-of-covid-19-core-industries-and-the-hispanic-workforce/>.

⁴ The Centers for Disease Control and Prevention provides a COVID Data Tracker on its website,

State's significant poverty percentage and be most impacted by the COVID-19 emergency, as required by the ARP Act.

Transparency

Statute: Section 312(d)(2)(B)(i) of the CRRSA Act requires an SEA to “distribute information about the [EANS] program to non-public schools and make the information . . . easily available.” Under 20 U.S.C. 1221e-3, the Secretary has the authority to promulgate rules governing the programs administered by the Department.

Final Requirements: Following approval of the Governor's ARP EANS application by the Secretary, an SEA must publish on its website, on or before the date it makes applications for services or assistance available to non-public schools, the State's approved (1) minimum percentage to determine whether a non-public school enrolls a significant percentage of students from low-income families; (2) source(s) of poverty data to be used in determining counts of students from low-income families in a non-public school; and (3) factors to determine whether a non-public school is most impacted by the COVID-19 emergency.

Reasons: We believe transparency regarding the significant poverty percentage, sources of poverty data, and factors for determining schools most impacted by the COVID-19 emergency that a State uses are important given the potential variations among States. Transparency would ensure that all stakeholders are aware of the specific criteria each State plans to apply in determining which non-public schools receive services or assistance under the ARP EANS program.

Determining Low-Income Counts

Low-Income Threshold

Statute: Under section 2002(a) of the ARP Act, services or assistance to non-public schools under the ARP EANS program are limited to “non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency.” Neither the ARP Act nor the CRRSA Act defines “students from low-income families” or “low-income students.”

Final Requirements: To be counted as a student from a low-income family for purposes of these requirements, a student must be aged 5 through 17 from a family whose income does not exceed 185 percent of the 2020 Federal poverty level.

Reasons: The Department defined the count of children as those aged 5

through 17 because that is the age range section 312(d)(1)(B) of division M of the CRRSA Act requires the Department to use to allocate EANS funds to States. Additionally, that age range is used in other contexts involving Federal education funds, including allocating funds to local educational agencies and determining the proportional share for equitable services under title I of the ESEA. (See, for example, sections 1117(c)(1) and 1124(c)(1) of the ESEA). The Department chose to set a limit on the poverty threshold for the family of a student to be counted as low-income at 185 percent of the 2020 Federal poverty level for several reasons. Section 312(d)(1)(B) of division M of the CRRSA Act requires the Department to allocate EANS funds to each State based on the proportion of children aged 5 through 17 “at or below 185 percent of poverty who are enrolled in non-public schools in the State.” The threshold to qualify for free and reduced-price meals under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*) is 185 percent of the Federal poverty level, and eligibility for free and reduced-price meals also is the poverty measure most often used for determining within-district allocations and for identifying the economically disadvantaged subgroup for accountability and reporting purposes under title I of the ESEA. One hundred eighty-five percent of the Federal poverty level is also the threshold to qualify for the E-rate program administered by the Federal Communications Commission (47 CFR 54.500, 54.505(b)). Finally, several commenters recommended 185 percent of the Federal poverty level as the threshold for family income. For these reasons, the Department believes it is the appropriate standard of low-income status for use in determining what constitutes a significant percentage of students from low-income families in non-public schools in order to provide services or assistance under the ARP EANS program.

Sources of Data on Family Income

Statute: Under section 2002(a) of the ARP Act, services or assistance to non-public schools under the ARP EANS program are limited to “non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency.” Neither the ARP Act nor the CRRSA Act defines the term “students from low-income families” or “low-income students.”

Final Requirements: Under the final requirements, to obtain a count of students from low-income families

enrolled in a non-public school, an SEA may use one or more of the following sources of data, provided the poverty threshold is consistent across sources and does not exceed 185 percent of the 2020 Federal poverty level: (1) Free or reduced-price lunch data; (2) data from the E-rate program; (3) data from a different source, such as scholarship or financial assistance data; or (4) data from a survey developed by the SEA.

Reasons: Free and reduced-price lunch data is the source of poverty data most aligned to 185 percent of the 2020 Federal poverty level. The Department recognizes, however, that many non-public schools do not participate in the Federal meals program. E-rate data are similarly aligned but also may not be available for many non-public schools. Accordingly, the Department includes other sources of data for an SEA to choose that should be more readily available to non-public schools. An SEA may also send a survey to non-public school families to collect poverty data for use in meeting the SEA's threshold for significant percentage of students from low-income families, provided the SEA has sufficient time to distribute, collect, and compile data from the surveys.

The final requirements afford an SEA some latitude to select one or more sources of poverty data, provided the poverty threshold is consistent among sources and does not exceed 185 percent of the Federal poverty level. Such latitude was particularly requested by commenters representing the non-public school community, given that not every school has the same poverty data on its families. The Department encourages an SEA to consult with non-public school officials regarding available sources of poverty data. Additionally, given that not all non-public schools have access to the same poverty data, the Department encourages an SEA to permit multiple sources of data, among schools or within a school, provided those data use a consistent poverty threshold.

Final Requirements

The Secretary establishes the following final requirements for the ARP EANS program:

(a) *In general.* A State educational agency (SEA) must provide services or assistance under the Emergency Assistance to Non-Public Schools (EANS) program, as authorized by the American Rescue Plan Act of 2021 (ARP Act), in accordance with the requirements applicable to the EANS program under section 312(d) of division M of the Coronavirus Response and Relief Supplemental

Appropriations Act, 2021 (CRRSA Act), except that—

(1) An SEA may provide such services or assistance only to an eligible non-public school that enrolls a significant percentage of students from low-income families and is most impacted by the COVID-19 emergency; and

(2) An SEA may not use such funds to provide reimbursements to any non-public school.

(b) *Determining non-public schools to be served.*

(1) To provide services or assistance to a non-public school under paragraph (a), an SEA must determine, consistent with the State's approved application for EANS funding under the ARP Act, that the school—

(i) Enrolls a significant percentage of students from low-income families in accordance with paragraphs (b)(2) and (c) of this section; and

(ii) Is most impacted by the COVID-19 emergency in accordance with paragraph (b)(3) of this section.

(2) A non-public school enrolls a significant percentage of students from low-income families if the percentage of students from low-income families enrolled in such school meets or exceeds—

(i) 40 percent; or

(ii) An alternate significant percentage approved by the Secretary in the State's application for EANS funding under the ARP Act that is based on circumstances in the State, which may be—

(A) The State's average percentage of students from low-income families in public and non-public schools;

(B) The average percentage of students from low-income families in non-public schools in the State that, for example, applied for or participated in the EANS program as authorized by the CRRSA Act; or

(C) Other factors that the State demonstrates support an alternate significant poverty percentage.

(3)(i) A non-public school is most impacted by the COVID-19 emergency based on one or more of the following factors—

(A) The number of COVID-19 infections per capita in the community or communities served by the non-public school;

(B) The number of COVID-19-related deaths per capita in the community or communities served by the non-public school;

(C) Data on the academic impact of lost instructional time and the social, emotional, and mental health impacts on students attending the non-public school attributable to the disruption of instruction caused by the COVID-19 emergency; or

(D) The economic impact of the COVID-19 emergency on the community or communities served by the non-public school.

(ii) In addition to using one or more of the factors identified in paragraph (b)(3)(i), an SEA may use other factors included in the State's approved application for EANS funding under the ARP Act to determine that a non-public school is most impacted by the COVID-19 emergency.

(4) An SEA must publish on its website, on or before the date it makes applications for EANS services or assistance under the ARP Act available to non-public schools, the State's approved—

(i) Minimum percentage to determine whether a non-public school enrolls a significant percentage of students from low-income families;

(ii) The source(s) of poverty data the State will use to determine counts of students from low-income families in a non-public school; and

(iii) Factors to determine whether a non-public school is most impacted by the COVID-19 emergency.

(c) *Determining low-income counts.*

(1) To be counted as a student from a low-income family for purposes of this section, a student must be aged 5 through 17 from a family whose income does not exceed 185 percent of the 2020 Federal poverty level.

(2) To obtain a count of students from low-income families enrolled in a non-public school under paragraph (c)(1), an SEA may use one or more of the following sources of data, provided the poverty threshold is consistent across sources—

(i) Data on student eligibility for free or reduced-price lunch under the Richard B. Russell National School Lunch Act (43 U.S.C. 1751 *et seq.*);

(ii) Data from the E-rate program administered by the Federal Communications Commission (47 CFR 54.500, 54.505(b));

(iii) Data from a different source, such as scholarship or financial assistance data; or

(iv) Data from a survey developed by the SEA.

Waiver of Notice and Comment Rulemaking and Delayed Effective Date

Under the Administrative Procedure Act (APA) (5 U.S.C. 551–559), the Department generally offers interested parties notice of and the opportunity to comment on proposed requirements. However, the APA provides that an agency is not required to conduct notice and comment rulemaking “when the agency for good cause finds . . . that notice and public procedure thereon are

impracticable, unnecessary, or contrary to the public interest.” (5 U.S.C. 553(b)(B)).

Here, there is good cause for waiving notice and comment rulemaking. Notice and comment rulemaking would be impracticable because the time involved would preclude emergency funds being available to meet exigent needs of non-public schools resulting from the COVID-19 emergency, including the provision of services to address the academic impact of lost instructional time among non-public school students. The COVID-19 emergency continues to present extraordinary circumstances, including widespread school closures, significant loss of instructional time, and trauma for students, educators, and other staff.

The final requirements provide reasonable parameters to address ambiguities regarding how to provide services or assistance to eligible non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the COVID-19 emergency. Accordingly, the final requirements are critical to ensuring that SEAs effectively and timely implement the ARP EANS program. In addition, the Department believes it is important to make clear the continued applicability of EANS requirements under the CRRSA Act, except as otherwise provided in the ARP Act. However, going through the full rulemaking process would delay the ability of SEAs to provide services or assistance to eligible non-public schools using ARP EANS funds, which are emergency funds intended to meet the immediate needs of non-public schools, including their students and teachers. Establishing these final requirements now, without the delay of notice and comment rulemaking, enables SEAs to effectively use ARP EANS funds to provide services or assistance to non-public schools to address the immediate safety and academic needs of students and help such schools safely return to or continue in-person instruction.

The Department has moved with urgency to publish this document in an expedited fashion to ensure timely availability of funds to non-public schools. The ARP Act was signed into law on March 11, 2021. Just one month later, on April 12, 2021, the Department published a request for information from the public to obtain comments that were due on April 26, 2021. After reviewing and considering the 66 comments received, the Department is publishing this document about two months after the comments were received.

Additionally, as noted above, the Department invited comment regarding implementation of the requirement “to provide services or assistance to non-public schools that enroll a significant percentage of [students from low-income families] and are most impacted by the [COVID-19] emergency” as part of the *Notice Inviting Applications and Announcing Allocations for the Emergency Assistance to Non-Public Schools Program Under the American Rescue Plan Act of 2021*, issued on April 12, 2021. The Department reviewed and considered the comments received in response to that notice in the development of these final requirements. That prior comment process and the Department’s responsiveness to those comments mitigate the need for notice-and-comment rulemaking in this context.

The APA also requires that regulations be published at least 30 days before their effective date, unless the agency has good cause to implement its regulations sooner. (5 U.S.C. 553(d)(3)). Again, because the ARP EANS funds are needed to address the immediate needs of students, educators, and schools due to the COVID-19 emergency, the Secretary also has good cause to waive the 30-day delay in the effective date of these requirements under 5 U.S.C. 553(d)(3).

Under the Congressional Review Act (CRA), a major rule may take effect no sooner than 60 calendar days after an agency submits a CRA report to Congress or the rule is published in the **Federal Register**, whichever is later. (5 U.S.C. 801(a)(3)(A)). However, the CRA creates limited exceptions to this requirement. (See 5 U.S.C. 801(c), 808). Section 808(2) provides that “any rule which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” As stated above, the Department has found good cause to issue these final requirements without notice-and-comment rulemaking, and thus we are not including the 60-day delayed effective date in this document.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and

Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities, in a material way (also referred to as “economically significant” regulations);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This regulatory action is an economically significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OMB’s Office of Information and Regulatory Affairs designated this rule as a “major rule,” as defined by 5 U.S.C. 804(2).

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account, among other things, and to the extent practicable, the costs of cumulative regulations;

(3) Select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including providing economic incentives—such as user fees or marketable permits—to encourage the

desired behavior, or providing information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

The Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action, and we are issuing these final requirements only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows and the reasons stated elsewhere in this document, the Department believes that the final requirements are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, or Tribal governments in the exercise of their governmental functions.

In this regulatory impact analysis, we discuss the need for regulatory action, the potential costs and benefits, and net budget impacts.

Elsewhere, under *Paperwork Reduction Act of 1995*, we identify and explain burdens specifically associated with information collection requirements.

Need for Regulatory Action

These final requirements are intended to clarify the provision of services or assistance to eligible non-public schools under the ARP EANS program. As discussed elsewhere in this document, the ARP EANS program provides significant resources to SEAs through each respective Governor to provide such services or assistance to respond to the unprecedented educational disruptions caused by the COVID-19 emergency. The Department believes this regulatory action is needed to ensure that SEAs provide services or assistance to non-public schools in a manner consistent with statutory requirements. In particular, the Department believes it is important to clarify the continued applicability of EANS requirements under the CRRSA Act, except as otherwise provided in the ARP Act. Additionally, the Department believes clarification is needed to

ensure that SEAs implement with fidelity the requirement to provide services or assistance only to eligible non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the COVID–19 emergency.

Analysis of Costs and Benefits

The Department believes this regulatory action does not impose significant new cost-bearing requirements on SEAs or other entities. This action primarily serves to clarify or give specific meaning to statutory requirements for SEAs in determining eligible non-public schools for services or assistance under the ARP EANS program; it generally does not establish new substantive requirements. Accordingly, costs associated with this action are attributable generally to the program statute. Moreover, in promulgating these final requirements, we have sought where possible to minimize the burden on SEAs in applying for ARP EANS funds and in complying with the statute. Any costs associated with the final requirements that are not directly attributable to the statute are outweighed by their benefits which, in addition to reduced burden, include clarity, appropriate flexibility, and transparency in SEA administration of the program.

Under the ARP EANS program, SEAs provide services or assistance to eligible non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the COVID–19 emergency. The final requirements establish that a non-public school enrolls a significant percentage of students from low-income families if the percentage of those students enrolled in the school meets or exceeds 40 percent or an alternate significant percentage approved by the

Secretary that is based on circumstances in the State. As discussed elsewhere in this document, 40 percent has long been recognized as a measure of significant poverty under title I of the ESEA. In addition to providing clarity, by using this percentage to determine whether a non-public school enrolls a significant percentage of students from low-income families, the final requirements employ a standard that is familiar to SEAs, thereby minimizing burden. By allowing an SEA to use an alternate significant percentage approved by the Secretary, the final requirements also provide appropriate flexibility to SEAs if circumstances in the State warrant a percentage other than 40 percent.

The final requirements also establish that a student is included in the count of students from low-income families enrolled in a non-public school if the student is aged 5 through 17 and from a family whose income does not exceed 185 percent of the 2020 Federal poverty level. This commonly used poverty threshold similarly minimizes the burden on SEAs in complying with the program statute while also providing clarity in program administration.

The final requirements further establish that, in determining which non-public schools are most impacted by the COVID–19 emergency, an SEA must use at least one of four identified factors, which notably include the numbers of COVID–19 infections and COVID–19-related deaths in communities served by the school. As discussed elsewhere in this document, community COVID–19 infection and death rates are readily available. Accordingly, the final requirements would allow an SEA to meet statutory requirements with minimal burden.

Lastly, the final requirements establish a new substantive requirement

on SEAs, namely, to provide transparency in program administration by publishing on the SEA website the minimum percentage used to determine whether a non-public school enrolls a significant percentage of students from low-income families, source(s) of poverty data, and the factors to be used to determine whether a school is most impacted by the COVID–19 emergency. We estimate that each SEA will need two hours to comply with this website posting requirement. At \$97.28 per hour (using mean wages for Education and Childcare Administrators ⁷ and assuming the total cost of labor, including benefits and overhead, is equal to 200 percent of the mean wage rate), the total estimated cost for 52 SEAs (including the District of Columbia and the Commonwealth of Puerto Rico) is approximately \$10,100.

Separately, the ARP EANS application imposes costs on SEAs. We estimate that each SEA will need two hours to complete the ARP EANS application. At \$97.28 per hour, the total estimated cost for 52 SEAs to complete the ARP EANS application is approximately \$10,100.

Net Budget Impacts

We estimate that the discretionary elements of these final requirements will not have an impact on the Federal budget. This regulatory action establishes requirements for SEAs receiving ARP EANS funds but does not affect the amount of funding available for this program. We anticipate that the \$2.75 billion in ARP EANS funds will be disbursed in Fiscal Year 2021, and therefore estimate \$2.75 billion in transfers in Fiscal Year 2021 relative to the pre-statutory baseline.

Accounting Statement

ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED IMPACTS
[in millions]

Category	Benefits
Clarity, flexibility, and transparency in SEA administration of ARP EANS program	Not quantified.
	Costs
Application completion and publication by SEAs of the minimum percentage used to determine whether a non-public school enrolls a significant percentage of students from low-income families, source(s) of poverty data, and the factors used to determine whether a school is most impacted by COVID–19.	\$0.02.
	Transfers
Services and assistance to non-public schools that enroll a significant percentage of students from low-income families and are most impacted by the COVID–19 emergency.	\$2,750.

⁷ See https://www.bls.gov/oes/current/oes_nat.htm.

Regulatory Flexibility Act Certification

The Regulatory Flexibility Act does not apply to this rulemaking because there is good cause to waive notice-and-comment rulemaking under the APA (5 U.S.C. 553).

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This helps ensure that the public understands the Department's collection instructions, respondents provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of the law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

As discussed in the *Analysis of Costs and Benefits* section of the *Regulatory Impact Analysis*, the Department believes this regulatory action does not impose significant new cost-bearing requirements on SEAs or other entities and that it primarily serves to clarify or give specific meaning to statutory requirements for SEAs. The final

requirements for determining non-public schools to be served and determining low-income counts allow SEAs to use generally available data and employ standards SEAs are familiar with, thereby minimizing cost and burden. The requirement that SEAs provide transparency in program administration, however, by publishing on their website the minimum percentage used to determine whether a non-public school enrolls a significant percentage of students from low-income families, the source(s) of poverty data, and the factors to be used to determine whether a school is most impacted by the COVID-19 emergency imposes a cost and burden hours on SEAs. In addition, the ARP EANS application will impose a cost and burden hours on SEAs. Those costs and burdens are discussed below.

For the final requirement to provide transparency in program administration by publishing on the SEA website the minimum percentage used to determine whether a non-public school enrolls a significant percentage of students from low-income families and the factors to be used to determine whether a school is most impacted by the COVID-19 emergency, we estimate that each SEA will need two hours to comply with the website posting requirement. At \$97.28 per hour, the total estimated cost for 52 SEAs (including the District of Columbia and the Commonwealth of Puerto Rico) is approximately \$10,100, and the total estimated burden is 104 hours.

We estimate that one application will be prepared by each eligible SEA and submitted through the Governor of the respective State. For the time to complete the application, we estimate that the number of burden hours per response will be two hours. The total estimated number of burden hours is

104 hours. At \$97.28 per hour, the total estimated cost for 52 SEAs to complete the ARP EANS application (including the District of Columbia and the Commonwealth of Puerto Rico) is also approximately \$10,100.

Collectively, we estimate that these new information collection activities will result in a total estimated cost of \$20,200 and a total estimated burden of 208 hours to the public annually. The Department is requesting an emergency paperwork clearance from OMB under 5 CFR 1320.13 on the OMB 1810-0741 data collection associated with these final requirements. That request will account for all burden hours and costs discussed within this section.

Consistent with 5 CFR 1320.8(d), the Department is also soliciting comments on the information collection. We must receive your comments on the collection activities contained in these final requirements on or before September 13, 2021. Comments related to the information collection activities must be submitted electronically through the Federal eRulemaking Portal at www.regulations.gov by selecting the Docket ID number ED-2021-SCC-0101 or via postal mail, commercial delivery, or hand delivery by referencing the Docket ID number and the title of the information collection request at the top of your comment. 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.

Note: The Office of Information and Regulatory Affairs and the Department review all comments related to the information collection activities posted at www.regulations.gov.

COLLECTION OF INFORMATION

Information collection activity	Estimated number responses	Hours per response	Total estimated burden hours	Estimated cost at an hourly rate of \$97.28
SEA Transparency	52	2	104	\$10,100
SEA ARP EANS Application	52	2	104	10,100
Annualized Total	104	4	208	20,200

Intergovernmental Review

The ARP EANS program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**,

individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3

file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the

Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or portable document format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs delegated the authority to perform the functions and duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021-14862 Filed 7-12-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED-2020-OSERS-0179]

Final Priority, Requirement, and Definitions—National Comprehensive Center on Improving Literacy for Students With Disabilities

AGENCY: Offices of Elementary and Secondary Education and Special Education and Rehabilitative Services, Department of Education.

ACTION: Final priority, requirement, and definitions.

SUMMARY: The Department of Education (Department) announces a priority, requirement, and definitions for the National Comprehensive Center on Improving Literacy for Students with Disabilities program (Comprehensive Centers program), Assistance Listing Number 84.283D. The Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA), requires the Secretary to establish a comprehensive center for students at risk of not attaining full literacy skills due to a disability. The Department may use the priority, requirement, and definitions for competitions in fiscal year (FY) 2021 and later years. We will use the priority, requirement, and definitions to award a cooperative agreement for a comprehensive center designed to improve literacy skills for students at risk of not attaining full literacy skills due to a disability.

DATES: Effective August 12, 2021.

FOR FURTHER INFORMATION CONTACT:

Kristen Rhoads, U.S. Department of Education, 400 Maryland Avenue SW, Room 5175, Potomac Center Plaza, Washington, DC 20202-5076. Telephone: (202) 245-6715. Email: Kristen.Rhoads@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The Comprehensive Centers program supports the establishment of not fewer than 20 comprehensive centers to provide capacity building services to State educational agencies (SEAs), regional educational agencies (REAs), local educational agencies (LEAs), and schools that improve educational outcomes for all students, close achievement gaps, and improve the quality of instruction. The purpose of the National Comprehensive Center on Improving Literacy for Students with Disabilities (Center) is to identify or develop evidence-based literacy assessment tools and professional development activities and identify evidence-based instruction, strategies, and accommodations for students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. The Center will also disseminate its products and information on evidence-based literacy to families, SEAs, LEAs, REAs, and schools.

Program Authority: Section 203 of the Educational Technical Assistance Act of 2002 (ETAA) (20 U.S.C. 9602) and section 2244 of the ESEA (20 U.S.C. 6674).

We published a notice of proposed priority, requirement, and definitions (NPP) for this program in the **Federal Register** on March 12, 2021 (86 FR 14048). The NPP contained background information and our reasons for proposing the particular priority, requirement, and definitions.

There are differences between the NPP and this notice of final priority, requirement, and definitions (NFP) as discussed in the *Analysis of Comments and Changes* section of this document. The substantive changes include not establishing a limit on reimbursement of indirect costs, adding a requirement related to features of screening assessments, and expanding who the Center involves when soliciting a

diversity of perspectives in the development and implementation of services.

Public Comment: In response to our invitation to comment in the NPP, 27 parties submitted comments on the proposed priority, requirement, and definitions.

Generally, we do not address technical and other minor changes. In addition, we do not address comments that raised concerns not directly related to the proposed priority, requirement, and definitions.

Analysis of Comments and Changes: An analysis of the comments and changes in the priority, requirement, and definitions since publication of the NPP follows.

The Department received 27 comments, which addressed several specific topics, including limiting reimbursement of indirect costs, supporting an external evaluator, meeting the needs of multiple populations and settings, implementing project services, measuring Center outcomes, and managing the Center and adequacy of resources. Each topic is addressed below.

General Comments

Comment: All commenters expressed overall support for the proposed Center. One commenter stressed the importance of this Center for addressing the needs of students in early childhood programs through 12th grade. Another commenter noted that the Center could be important for ensuring quality education and creating equitable learning environments for students with disabilities in both charter and traditional public schools.

Discussion: The Department appreciates the comments and agrees with the commenters. The Center to be funded under this program will provide necessary and valuable technical assistance (TA) related to improving literacy outcomes for students at risk of not attaining full literacy skills due to a disability.

Changes: None.

Comment: One commenter suggested removing language related to competing in the global economy. The reviewer thought that the phrase adds undue stress for students with disabilities.

Discussion: The mission of the Department includes “promoting student achievement and preparation for global competitiveness.” This mission applies to all students, including students with disabilities and we think it is a reasonable expectation to have a broad goal of preparing all students for the global economy.

Changes: None.

Directed Question 1—Limiting Reimbursement of Indirect Costs

Comment: Commenters had differing opinions on whether the Department should limit the reimbursement of indirect costs. Two commenters were opposed to establishing a limit on reimbursement of indirect costs or a cap. They stated that a limit would reduce the number of qualified applicants, which would correspondingly reduce competition. Specifically, the two commenters noted that a limit would make it cost prohibitive for some organizations to compete for the grant, as they may not be able to absorb any unrecovered indirect costs. They also expressed concerns that the implementation of an indirect cost rate limit would not impact each applicant equally or result in equal savings to the government because categories of indirect costs vary across organizations. Finally, the commenters noted that indirect costs are established and audited through a lengthy and rigorous process administered by the cognizant agency and that the already negotiated rate should be appropriate for this program.

In contrast, three commenters supported establishing a cap on the indirect cost rate. One commenter supported the range of 20 to 35 percent proposed by the Department. Another commenter recommended a rate between 45 and 55 percent. The third commenter wanted to know the percentage of current grantees that had indirect cost rates higher than 35 percent and recommended increasing the cap if that percentage was high.

One commenter sought clarification on how the Department defined administrative costs if the Department set a limit to indirect cost reimbursement.

Discussion: The Department appreciates the stakeholder input it received in response to the directed question on the Department's considering potentially limiting indirect costs. We considered this potential requirement based on 2 CFR 200.414(c)(1), which allows a Federal awarding agency to use an indirect cost rate different from the negotiated rate when required by Federal statute or regulation or when approved by a Federal awarding agency head based on documented justification when the Federal awarding agency implements, and makes publicly available, the policies, procedures, and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates. Federal discretionary grantees have

often historically been reimbursed for indirect costs at the rate that each grantee negotiates with its cognizant Federal agency. At this time, given the mixed and limited public comments and upon further reflection, the Department has decided not to impose a limit on the indirect costs for this competition and relies instead on the negotiated rate process with cognizant Federal agencies.

Changes: The final requirement does not include an indirect cost rate cap.

Directed Question 2—Supporting an External or Third-Party Evaluator

Comment: Commenters had differing opinions on the value of an external or third-party evaluator. Some commenters stated that an external or third-party evaluator would result in a high-quality impartial evaluation of the Center's success and improve the quality of the Center services and products.

Other commenters did not think that an external or third-party reviewer was necessary. One commenter noted that the role of the evaluator and expectations for evaluation are more important than whether the evaluator was internal or external to the Center. The commenter noted that the currently funded projects in the Comprehensive Centers Program Network successfully utilize a variety of evaluation approaches involving external and internal evaluators.

Two commenters noted that an external evaluator would unnecessarily divert funds from other Center activities. Both commenters noted that providing crucial TA to teachers and educators should be prioritized over evaluation activities. One commenter stated that an external evaluator would also divert funds from conducting important formative evaluation activities to determine the quality, relevance, and usefulness of the Center's work and that the size of the award, in general, was not sufficient for conducting a rigorous evaluation of Center activities. One commenter pointed out that in a post-pandemic climate, having more funds dedicated to services may be particularly important given that students would likely have more academic needs when they return to in-person instruction. This commenter recommended exploring low-cost evaluation efforts such as the Department conducting the evaluation.

Discussion: The Department agrees with the commenters who recommend requiring a third-party or external evaluator. A third-party or external evaluator will provide objectivity and credibility in evaluating the Center's success; provide input to Center staff to

support mid-course corrections; bring additional technical expertise in evaluation methodology, statistics, or related topics; and allow Center staff to devote their attention to project implementation. Despite potentially diverting funds from important TA services or products, a third-party or external evaluator will be crucial for developing and implementing a strong evaluation plan and ensuring the effectiveness of those TA services and products that are provided and developed.

Changes: None.

Comment: One commenter asked whether the Center would be independent from or integrated with the current Comprehensive Centers Program Network. Specifically, the commenter wanted to know whether the Center would be part of the evaluation of the Comprehensive Centers program being conducted by the Department's Institute of Education Sciences (IES) and required to utilize the network's evaluation-related resources and data collection protocols and activities.

Discussion: The Department will encourage collaboration between the Center and the network; however, the Center will have its own set of requirements. It will not be part of the Comprehensive Centers program evaluation conducted by IES. Similarly, the network's evaluation-related resources and data collection protocols and activities will not be required, though the Department encourages applicants to consider adopting or adapting them as part of their evaluation work. The resources will be shared with the Center when funded, and the Department will work with the Center and its third-party evaluator in aligning its evaluation plan.

Changes: None.

Meeting the Needs of Multiple Populations and Settings

Comment: One commenter recommended adopting a definition of the term "families" that includes the variety of individuals who care for and interact with students with disabilities in their home lives.

Discussion: The Department agrees that a variety of individuals care for, interact with, and play important roles in the lives of children and students with disabilities in their home lives. We decline to define the term "families" because we understand that family structures may vary and encompass individuals with different relationships to each other.

Changes: None.

Comment: One commenter noted gender differences and potential referral

bias in identification of reading disabilities with male students being identified more often than female students. The commenter recommended additional language be added to the notice to ensure that females receive adequate testing, attention, and resources.

Discussion: The Department thanks the commenter for the comment and recognizes that gender differences and referral bias in identification of disabilities have been documented in the research literature. While the Center will not be evaluating or identifying students as having a disability, the priority requires the Center to ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, sex, age, or disability. The grantee will ensure that products and services meet the needs of these recipients.

Changes: None.

Comment: Two commenters observed that the priority specifically named dyslexia and did not address other disability categories. One commenter asked if other disability categories would be included or excluded from Center activities. The second commenter recommended expanding the focus of the Center to address the literacy needs of students with Attention-Deficit/Hyperactivity Disorder and Autism Spectrum Disorder. The commenter noted that children with these disabilities also struggle with attaining full literacy skills and, therefore, need to receive evidence-based literacy practices.

Discussion: The Department agrees that students from a variety of disability groups do not attain full literacy skills due to their disabilities and require evidence-based instructional and assessment practices. Section 2244 of the ESEA (20 U.S.C. 6674) requires that the Center address the needs of students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. In meeting this requirement, an applicant could include students with Attention-Deficit/Hyperactivity Disorder, Autism Spectrum Disorder, or other disabilities.

Changes: None.

Comment: One commenter recommended defining the term “dyslexia” using the definition in the Formerly Incarcerated Reenter Society Transformed Safely Transitioning Every Person Act (First Step Act). The commenter noted that the definition in

the First Step Act is the most up-to-date definition of dyslexia and the only definition of dyslexia in Federal statute.

Discussion: The Department thanks the commenter for the comment. Neither ESEA nor the Individuals with Disabilities Education Act (IDEA) includes a definition of dyslexia. Dyslexia is identified as an example of a condition that could enable a student to be eligible under IDEA’s specific learning disability category. In addition, States have developed their own definitions of dyslexia.

Changes: None.

Comment: One commenter recommended adopting the definition of “dyslexia screening program” from the First Step Act noting that the Center should provide TA and disseminate information on screeners that are evidence-based, psychometrically valid, affordable to schools, efficient to scale, and readily available to use as soon as possible.

Discussion: The Department agrees that screening assessments for dyslexia and other literacy-related disabilities should have the features that the reviewer described. Instead of adopting the definition from the First Step Act, the Department has added a requirement in the Quality of Project Services section of the priority. The requirement states that applicants should address the current research on screening assessments for dyslexia and other literacy-related disabilities that are evidence-based, psychometrically valid, free or low-cost, efficient to scale, and readily available for use.

Changes: The Department has added a requirement related to the features of screening assessments in paragraph (b)(4)(ii) of the Quality of Project Services section.

Comment: One commenter recommended that the Center have a greater focus on meeting the needs of teachers and students who are participating in remote learning environments due to the current novel coronavirus 2019 (COVID–19) pandemic.

Discussion: The Department thanks the commenter for the comment and recognizes the unique challenges that students, teachers, and schools are experiencing due to COVID–19 as well as the critical role that remote learning plays when regular classroom instruction is disrupted. The priority is for improving the implementation of evidence-based literacy practices in teacher classroom and remote learning environments. The grantee will ensure that products and services meet the needs of teachers and students in both types of environments.

Changes: None.

Comment: One commenter was concerned that the Center may not meet the needs of charter schools noting that charter schools may differ from traditional public schools and districts. The commenter recommended requiring descriptions of plans to reach charter schools and evaluating proposals for the quality of their charter school plan.

Discussion: The Department thanks the commenter for the comment and agrees that appropriately serving students with disabilities is often an issue for charter schools. The Center should address the needs of all schools serving students with disabilities. As such, applicants should propose to develop TA products and services that address the needs of students in charter schools. Applicants could include a plan in Appendix A of their application. However, we do not believe it is necessary to require a plan to reach charter schools or evaluate proposals based on the quality of this plan.

Changes: None.

Implementing Project Services

Comment: One commenter noted that institutions of higher education pre-service training programs are not specified as recipients of intensive, sustained TA. The commenter pointed out that pre-service teachers need training in the science of reading and that State governments are examining college preparation programs in this area. The commenter noted that this Center could be a major catalyst in supporting this work.

Discussion: Section 2244(b)(5) of ESEA requires the Center to disseminate its products to regionally diverse SEAs, REAs, LEAs, and schools, including, as appropriate, through partnerships with other comprehensive centers established under section 203 of the Educational Technical Assistance Act of 2002 (20 U.S.C. 9602), and regional educational laboratories established under section 174 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9564). The products developed by the Center could be disseminated to and used in pre-service training programs.

Changes: None.

Comment: Three commenters noted the importance of collaboration and outreach to other federally funded Centers as well as professional organizations and associations with literacy expertise, who represent disability groups, or who represent educators and service providers for students with disabilities. One commenter recognized that in special education, there is often a lack of collaboration between special education

and other educators when sharing expertise and resources. Another commenter noted that at least a dozen currently funded Regional Comprehensive Centers include literacy as part of their intensive, high-leverage capacity building TA and that well-planned collaboration between those centers and this Center would benefit TA providers and TA recipients. One commenter encouraged early outreach to related professional organizations.

Discussion: The Department agrees that coordination between this Center and other federally funded TA projects focused on literacy as well as early outreach to related professional organizations would benefit the Center and its TA recipients. The Department will work with the Center to facilitate coordination and collaboration with similar Department-funded projects and professional organizations focused on improving literacy for students with disabilities.

Changes: None.

Comment: One commenter recommended embedding implicit bias training in Center activities, noting that implicit bias about individuals with disabilities is pervasive in society.

Discussion: The Department thanks the commenter and agrees that individuals with disabilities face implicit bias in school and life. As part of addressing the needs of students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning, an applicant could also include implicit bias training as part of its TA.

Changes: None.

Comment: One commenter recommended requiring that the Center conduct a review of States that have passed laws related to screening and instruction for students with dyslexia and tailoring TA to aid effective implementation of these laws.

Discussion: We do not believe that it is necessary to require this activity. The priority requires the Center to address current and emerging training and information needs of SEAs, REAs, LEAs, TA centers, schools, and practitioners related to selecting and implementing classroom and remote learning environment evidence-based practices (EBPs) that will improve literacy outcomes for students with disabilities, including students with dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive

functioning. It is expected that applicants will have knowledge of State laws related to screening and instruction for dyslexia. In addition, the grantee will provide targeted, specialized TA to a variety of recipients, including SEAs, as part of its project services. This targeted, specialized TA could include conducting a review of State laws and tailoring TA for SEAs based on their needs.

Changes: None.

Measuring Center Outcomes

Comment: One commenter recommended requiring parent or family perspectives or feedback as a Center outcome measure.

Discussion: The Center is required to provide TA to a variety of recipients including parents or families, SEAs, REAs, LEAs, schools, Head Start, and other early childhood programs and ensure that the products and services meet the intended recipients. In meeting these requirements, an applicant could include family or parent perspectives, including perspectives from organizations such as the OSEP-funded Parent Training and Information Centers, or feedback as a Center outcome measure. However, we do not believe it is necessary that perspectives or feedback from any of the recipients be required as a Center outcome measure.

Changes: None.

Comment: One commenter suggested requiring improvement in noncognitive skills, such as effort, curiosity, inquisitiveness, as a Center outcome.

Discussion: The Department recognizes the importance of noncognitive skills for student achievement. While the Center is required to address literacy outcomes, an applicant could also include noncognitive skills as part of its project services and evaluation. We do not believe that it is necessary to require noncognitive skills as a Center outcome.

Changes: None.

Managing the Center and Adequacy of Resources

Comment: Two commenters addressed the requirement that the project director should be, at minimum, 0.5 full-time equivalency (FTE) throughout the project. One commenter asked whether it would be permissible to split the 0.5 FTE for the project director and distribute the FTE at the applicant's discretion to other Center personnel or co-project directors. The second commenter noted that the complexity of the scope of work requires a substantial involvement of leadership and expertise in order to

result in a successful Center. This commenter recommended requiring a project director at a minimum of 0.75 FTE or two co-project directors at a minimum of 0.5 FTE each or a project director at a minimum of 0.5 FTE and a deputy director at 0.75–1.0 FTE.

Discussion: The Department believes that it is necessary to have a single project director responsible for understanding and coordinating Center's activities to ensure that they are conducted effectively and efficiently. Accordingly, the Department agrees that the project director should dedicate significant time to this Center. Based on the Department's experience with this Center, having one project director at a minimum of 0.5 FTE is necessary to oversee the Center's complex and overlapping activities and produce high-quality, relevant products and services that have strong scientific integrity. The Department also agrees that any co-project directors or deputy directors should also have a significant time investment in the project; however, the applicant can distribute the FTE of other Center personnel at its discretion.

Changes: None.

Comment: One commenter encouraged the Center to incorporate input from a variety of educators, including general education teachers, special education teachers, librarians, paraprofessionals, and specialized instructional support personnel, who serve a broad diversity of students in the Center activities. The commenter noted that educators offer valuable perspectives on specific types of literacy instruction to best address the differing populations of students they serve.

Discussion: The Department thanks the commenter and agrees that educators bring critical perspectives related to all Center services and activities. The proposed priority required applicants to address how the project will benefit from a diversity of perspectives, including those of families, general and special education teachers, TA providers, researchers, institutions of higher education, and policy makers, among others, in its development and operation as part of the Quality of the Management Plan requirements. We agree that expanding those requirements to include paraprofessionals, principals, other school leaders, and specialized instructional support personnel would improve Center services and activities.

Changes: Paraprofessionals, principals, other school leaders, and specialized instructional support personnel were added to paragraph (e)(4) of the final Priority as groups to provide diverse perspectives that will

benefit the development and operation of the Center.

Comment: One commenter asked if the notice inviting applications would require cost sharing and, if not, would the Department provide more detail about its expectations for or examples of how applicants could use non-project resources in paragraph

(b)(5)(iv)(D)(6)(iii) of the final Priority to achieve the intended project outcomes.

Discussion: Cost sharing is not required in this program. Examples of ways to use non-project resources include the following: Using in-kind contributions of FTE from project staff, expert consultants, or communications specialists; utilizing, adapting, and disseminating previously developed high-quality resources, web-based products, services, or questionnaires; and establishing partnerships with professional organizations to assist with disseminating information to a broader audience.

Changes: None.

Final Priority:

National Comprehensive Center on Improving Literacy for Students with Disabilities.

Background:

Section 2244 of the ESEA requires the Secretary to establish a comprehensive center on students at risk of not attaining full literacy skills due to a disability. Comprehensive centers are typically administered by the Office of Elementary and Secondary Education (OESE). OESE is funding this Center; however, because of the Center's subject matter, it will be administered jointly by OESE and OSEP in the Office of Special Education and Rehabilitative Services (OSERS).

The project is designed to improve implementation of evidence-based literacy practices in both teacher classroom and remote learning environments. With respect to remote learning, the priority is intended to ensure that teachers have the training and support they need to implement evidence-based literacy practices during remote instruction for students with disabilities, including students with dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. Remote learning plays a critical role in regular instruction and can serve as a crucial link allowing high-quality teaching and learning to continue when regular instruction is disrupted.

Priority:

The purpose of this priority is to fund a cooperative agreement to establish and operate a National Comprehensive

Center on Improving Literacy for Students with Disabilities (Center) for children in early childhood education programs through high school. The Center must—

(a) Identify or develop free or low-cost evidence-based assessment tools for identifying students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning;

(b) Identify evidence-based literacy instruction, strategies, and accommodations, including assistive technology, designed to meet the specific needs of such students;

(c) Provide families of such students with information to assist such students;

(d) Identify or develop evidence-based professional development for teachers, paraprofessionals, principals, other school leaders, and specialized instructional support personnel to—

(1) Understand early indicators of students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning;

(2) Use evidence-based screening assessments for early identification of such students beginning not later than kindergarten;¹ and

(3) Implement evidence-based instruction designed to meet the specific needs of such students; and

(e) Disseminate the products of the comprehensive center to regionally diverse SEAs, REAs, LEAs, and schools, including, as appropriate, through partnerships with other comprehensive centers established under section 203 of the Educational Technical Assistance Act of 2002 (20 U.S.C. 9602), and regional educational laboratories established under section 174 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9564).

In addition to these programmatic requirements, to be considered for funding under this priority, applicants must meet the application and administrative requirements in this priority, which are:

(a) Demonstrate, in the narrative section of the application under "Significance," how the proposed project will—

¹ Applicants are encouraged to identify or develop professional development for using evidence-based screening assessments for early identification of children in early childhood or prekindergarten programs as well.

(1) Address current and emerging training and information needs of SEAs, REAs, LEAs, TA centers, schools, and practitioners to select and implement teacher classroom and remote learning environment evidence-based practices (EBPs) that will improve literacy outcomes for students with disabilities, including students with dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. To meet this requirement, the applicant must—

(i) Demonstrate knowledge of current and emerging EBPs, which can be used in reading and literacy-related teacher classroom and remote learning environment instruction, screening, assessment, and identification or diagnosis of students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. This includes demonstrating knowledge of current and emerging reading and literacy-related EBPs for students who are English learners; students from a variety of settings (e.g., rural, suburban, urban); students from low-income families; and other educationally disadvantaged students; or

(ii) Demonstrate knowledge of, previous experience with, and results of using creative approaches and implementing in-person and virtual TA strategies to provide capacity-building services and disseminate teacher classroom and remote learning environment EBPs to a variety of entities, including parents, SEAs, REAs, LEAs, schools, Head Start, and other early childhood programs;

(2) Demonstrate a record of improving outcomes in literacy achievement for students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning, in order to better prepare them to compete in a global economy; and

(3) Demonstrate a record of improving the adoption, implementation, and sustainment of teacher classroom and remote learning environment EBPs in literacy instruction for students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing,

comprehension, or executive functioning.

(b) Demonstrate, in the narrative section of the application under “Quality of project services,” how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, sex, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that products and services meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended short-term, intermediate, and long-term outcomes. To meet this requirement, the applicant must provide—

(i) A five-year plan for the Center to identify current and emerging training and information needs and to address the priority;

(ii) Measurable intended project outcomes; and

(iii) In Appendix A, the logic model (as defined in 34 CFR 77.1) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended short-term, intermediate, and long-term outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, and describe any underlying concepts, assumptions, expectations, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: www.osepideasthatwork.org/logicModel, www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework, and www.federalregister.gov/d/2019-06583.

(4) Be based on current research and make use of EBPs in the development and delivery of its products and services. To meet this requirement, the applicant must describe—

(i) The current research on teacher classroom and remote learning environment EBPs for literacy instruction for students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning;

(ii) The current research on teacher classroom and remote learning environment EBPs for assessing students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. This should include the current research on screening assessments for dyslexia and other literacy-related disabilities that are evidence-based, psychometrically valid, free or low-cost, efficient to scale, and readily available for use; and

(iii) The current research about adult learning principles in in-person and virtual settings and implementation science that will inform the proposed TA; and

(5) Develop products or refine or update publicly available existing products and provide in-person and virtual services that are of high quality and sufficient intensity and duration to achieve the intended measurable outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify or develop the knowledge base in teacher classroom and remote learning environment literacy instruction for students at risk of not attaining full literacy skills due to a disability;

(ii) Its proposed approach to universal, general TA, which must identify the intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(iii) Its proposed approach to targeted, specialized TA, which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services under this approach, a description of new or existing publicly available products that may be used and services that the Center proposes to make available, and the expected impact of those products and services under this approach; and

(B) Its proposed approach to measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the local level; and

(iv) Its proposed approach to intensive, sustained TA, which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services, a description of new or existing publicly available products that may be used and services that the

Center proposes to make available, and the expected impact of those products and services under this approach;

(B) Its proposed approach to measure the readiness of the target audiences to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability to build capacity at the SEA, REA, LEA, school, and early childhood education program levels;

(C) Its proposed plan for assisting SEAs, REAs, and LEAs to build or enhance in-person and virtual training systems that include capacity-building services and professional development based on adult learning principles and coaching; and

(D) Its proposed plan for working with appropriate levels of the education system (e.g., SEAs, regional TA providers, districts, schools, early childhood education programs, families) to ensure that there is communication between each level and that there are systems in place to support the use of teacher classroom and remote learning environment EBPs for literacy instruction;

(6) Partner with the National Comprehensive Center and at least one of the other federally funded comprehensive centers, regional educational laboratories, equity assistance centers, OSEP- and other related federally funded TA Centers, parent training and information and community parent resource centers funded by the Department and OSEP (e.g., Center for Parent Information and Resources and Parent Technical Assistance Centers), and other related organizations to refine or develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes; and

(7) Develop a dissemination plan that describes how the applicant will systematically distribute information, products, and services to varied intended audiences, using a variety of in-person and virtual dissemination strategies, to promote awareness and use of the Center's products and services.

(c) In the narrative section of the application under “Quality of the project evaluation,” include an evaluation plan for the project

developed in consultation with and implemented by a third-party evaluator. The evaluation plan must—

(1) Articulate formative and summative evaluation questions, including important process and outcome evaluation questions, that are linked directly to the project's proposed logic model required in paragraph (b)(2)(iii) of this notice;

(2) Describe how progress in and fidelity of implementation, as well as project short-term, intermediate, and long-term outcomes, will be measured to answer the evaluation questions. Specify the measures and associated instruments or sources for data appropriate to the evaluation questions. Include information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and improve service delivery over the course of the project and to refine the proposed logic model and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation and include staff assignments for completing the plan. The timeline must indicate that the data will be available annually for the annual performance report (APR); and

(5) Dedicate sufficient funds in each budget year to cover the costs of developing or refining the evaluation plan in collaboration with a third-party evaluator and the costs associated with the implementation of the evaluation plan by the third-party evaluator.

(d) Demonstrate, in the narrative section of the application under "Adequacy of resources and quality of project personnel," how—

(1) The proposed project will ensure equal access for employment for all, including those who are members of groups that have traditionally been underrepresented based on race, color, national origin, sex, age, religion, or disability;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications, subject-matter expertise, and technical experience to carry out the proposed activities, achieve the project's intended outcomes, and develop ongoing partnerships with leading experts and organizations nationwide to inform project activities;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under "Quality of the management plan," how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes. The identified project director should be, at minimum, 0.5 full-time equivalency throughout the project period;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, general and special education teachers, paraprofessionals, principals, other school leaders, specialized instructional support personnel, TA providers, researchers, institutions of higher education, and policy makers, among others, in its development and operation.

(f) Address the following additional application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, or virtually, after receipt of the award, and an annual planning meeting in Washington, DC, or virtually, with the OSEP project officer, OESE staff, and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative;

(ii) A two and one-half day project directors' conference in Washington, DC, or a virtual conference, during each year of the project period;

(iii) Two annual two-day trips to attend Department briefings, Department-sponsored conferences, and

other meetings, as requested by OSEP; and

(iv) At least monthly, communicate and collaborate with other Department-funded centers to achieve project objectives;

(3) Include, in the budget, a line item for an annual set-aside of 5 percent of the grant amount to support emerging needs that are consistent with the proposed project's intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(4) Include a plan for maintaining a high-quality website, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility;

(5) Include a plan for ensuring that annual project progress toward meeting project goals is posted on the project website;

(6) Include, in Appendix A, a letter of agreement from each partnering organization or consultant. The letter of agreement should clearly specify the role of the partnering organization or consultant and the time needed to fulfill the commitment to the project; and

(7) Include, in Appendix A, an assurance to assist OSEP and OESE with the transfer of pertinent resources and products and to maintain the continuity of services to target audiences during the transition to this new award period and at the end of this award period, as appropriate.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the

priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Definitions:

The Department establishes the following definitions for the purposes of the National Comprehensive Center on Improving Literacy for Students with Disabilities Program. We may apply one or more of these definitions in any year in which this program is in effect. We include the source of each definition in parentheses.

Capacity-building services means assistance that strengthens an individual's or organization's ability to engage in continuous improvement and achieve expected outcomes. (Final Priorities, Requirements, Definitions, and Performance Measures; Comprehensive Centers Program (84 FR 13122), April 4, 2019.)

Fidelity means the delivery of instruction in the way in which it was designed to be delivered. (Final Priorities and Definitions; State Personnel Development Grants (77 FR 45944), August 2, 2012.)

Intensive, sustained TA means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

Regional educational agency, for the purposes of this program, means "Tribal Educational Agency" as defined in ESEA section 6132(b)(3), as well as other educational agencies that serve regional areas. (Final Priorities, Requirements, Definitions, and Performance Measures; Comprehensive Centers Program (84 FR 13122), April 4, 2019.)

TA services are defined as negotiated series of activities designed to reach a valued outcome.

Targeted, specialized TA means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of

practice can also be considered targeted, specialized TA.

Third-party evaluator is an independent and impartial program evaluator who is contracted by the grantee to conduct an objective evaluation of the project. This evaluator must not have participated in the development or implementation of any project activities, except for the evaluation activities, nor have any financial interest in the outcome of the evaluation.

Universal, general TA means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

Note: This notice does *not* solicit applications. In any year in which we choose to use this priority and these requirements and definitions, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563 Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) determines whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a "major rule," as defined by 5 U.S.C. 804(2).

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing the final priority, requirement, and definitions only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory

action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with these Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Discussion of Potential Costs and Benefits

The Department believes that the costs associated with this final priority, requirement, and definitions will be minimal, while the benefits are significant. The Department believes that this regulatory action does not impose significant costs on eligible entities. Participation in this program is voluntary, and the costs imposed on applicants by this regulatory action will be limited to paperwork burden related to preparing an application. The benefits of implementing the program—improving literacy skills for students at risk of not attaining full literacy skills due to a disability—will outweigh the costs incurred by applicants, and the costs of carrying out activities associated with the application will be paid for with program funds. For these reasons, we have determined that the costs of implementation will not be excessively burdensome for eligible applicants, including small entities.

Regulatory Alternatives Considered

The Department believes that the priority, and requirement, and definitions are needed to administer the program effectively.

Paperwork Reduction Act of 1995

The final priority, requirement, and definitions contain information collection requirements that are approved by OMB under control number 1894-0006; the final priority, requirement, and definitions do not affect the currently approved data collection.

Regulatory Flexibility Act Certification: The Secretary certifies that this final regulatory action would not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration (SBA) Size Standards define proprietary institutions as small businesses if they are independently owned and operated,

are not dominant in their field of operation, and have total annual revenue below \$7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The small entities that this final regulatory action will affect are SEAs; LEAs, including charter schools that operate as LEAs under State law; institutions of higher education (IHEs); other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations. We believe that the costs imposed on an applicant by the final priority, requirement, and definitions will be limited to paperwork burden related to preparing an application and that the benefits of this final priority, requirement, and definitions will outweigh any costs incurred by the applicant.

Participation in the National Comprehensive Center on Improving Literacy for Students with Disabilities program is voluntary. For this reason, the final priority, requirement, and definitions will impose no burden on small entities unless they applied for funding under the program. We expect that in determining whether to apply for National Comprehensive Center on Improving Literacy for Students with Disabilities program funds, an eligible entity will evaluate the requirements of preparing an application and any associated costs and weigh them against the benefits likely to be achieved by receiving a National Comprehensive Center on Improving Literacy for Students with Disabilities program grant. An eligible entity will most likely apply only if it determines that the likely benefits exceed the costs of preparing an application.

We believe that the final priority, requirement, and definition will not impose any additional burden on a small entity applying for a grant than the entity would face in the absence of the final action. That is, the length of the applications those entities would submit in the absence of the final regulatory action and the time needed to prepare an application will likely be the same.

This final regulatory action will not have a significant economic impact on a small entity once it receives a grant because it would be able to meet the costs of compliance using the funds provided under this program.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

David Cantrell,

Deputy Director, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021-14865 Filed 7-9-21; 11:15 am]

BILLING CODE 4000-01-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R09–OAR–2020–0414; FRL–10024–74–Region 9]

Air Plan Approval; California; Sacramento Metropolitan Air Quality Management District**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Sacramento Metropolitan Air Quality Management District (SMAQMD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of oxides of nitrogen (NO_x) from water heaters, boilers, and process heaters. We are approving a local rule that regulates

these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on August 12, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2020–0414. 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:

Robert Schwartz, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3286 or by email at schwartz.robert@epa.gov.

SUPPLEMENTARY INFORMATION:

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

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
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I. Proposed Action

On April 21, 2021 (86 FR 20645), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule #	Rule title	Amended	Submitted
SMAQMD	414	Water Heaters, Boilers and Process Heaters Rated Less Than 1,000,000 Btu per Hour.	10/25/2018	01/23/2019

We proposed to approve this rule because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA’s proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP. The October 25, 2018 version of Rule 414 will replace the previously approved version of this rule in the SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SMAQMD rule described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through www.regulations.gov and at the EPA Region IX Office (please contact the person identified in the **FOR**

FURTHER INFORMATION CONTACT section of this preamble for more information).

V. Statutory and Executive Order Reviews

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 September 13, 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.

Dated: July 1, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(388)(i)(D)(6) and (c)(545)(i)(B) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(388) * * *

(i) * * *

(D) * * *

(6) Previously approved on November 1, 2011 in paragraph (c)(388)(i)(D)(2) of this section and now deleted with replacement in (c)(545)(i)(B)(1), Rule 414, "Water Heaters, Boilers and Process Heaters Rated Less Than 1,000,000 BTU per hour," amended on March 25, 2010.

* * * * *

(545) * * *

(i) * * *

(B) Sacramento Metropolitan Air Quality Management District.

(1) Rule 414, "Water Heaters, Boilers and Process Heaters Rated Less Than 1,000,000 BTU per hour," amended on October 25, 2018.

(2) [Reserved]

* * * * *

[FR Doc. 2021-14526 Filed 7-12-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0228; FRL-8663-01-OCSP]

Fluxapyroxad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluxapyroxad in or on the cottonseed subgroup 20C, the fruiting vegetable group 8-10, the pome fruit group 11-10, and pomegranate. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 13, 2021. Objections and requests for hearings must be received on or before September 13, 2021 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0228, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301

Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions

provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0228 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before September 13, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0228, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 30, 2020 (85 FR 61681) (FRL-10014-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8825) by IR-4, IR-4 Project Headquarters Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that EPA establish tolerances in 40 CFR part 180 for residues of fluxapyroxad, (BAS 700 F); 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide, its metabolites, and degradates in or on the raw agricultural commodities: Pomegranate at 0.2 ppm; vegetable, fruiting, group 8–

10 at 0.7 ppm; fruit, pome, group 11–10 at 0.8 ppm; and cottonseed subgroup 20C at 0.3 ppm. The petition also requested to remove the established tolerances for fluxapyroxad in or on fruit, pome, group 11; vegetables, fruiting, group 8; and cotton, undelinted seed. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing one tolerance at a different level than requested. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluxapyroxad including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with fluxapyroxad follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not

vary between tolerance rulemakings and republishing the same sections is unnecessary; EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for fluxapyroxad, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluxapyroxad and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of fluxapyroxad, see Unit III.A. of the May 5, 2016 rulemaking (81 FR 27019) (FRL-9945-48).

Toxicological Points of Departure/Levels of Concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the May 5, 2016 rulemaking.

Exposure Assessment. Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. The updates are discussed in this section; the remaining discussion of EPA’s assumptions for exposure remain unchanged since the 2016 rulemaking. For a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the May 5, 2016 rulemaking.

EPA’s dietary exposure assessments have been updated to include the additional exposure from the new use of fluxapyroxad on pomegranate, and the crop group expansions to the cottonseed subgroup 20C, the fruiting vegetable group 8–10, and the pome fruit group 11–10. A partially refined acute dietary exposure analysis was performed for the general population and all population subgroups. Tolerance-level residues adjusted to account for the metabolite of concern (M700F008) and 100 percent crop treated (PCT) assumptions were used for all plant commodities. For livestock commodities, anticipated residues accounting for parent and the metabolites of concern (M700F008 and/or M700F010) were used. A moderately refined chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Average field trial residues for parent plus maximum metabolite

residue were used for all plant commodities. For livestock commodities anticipated residues accounting for parent and the metabolites of concern (M700F008 and/or M700F010) were used. An assumption of 100 PCT was also used for the chronic dietary analysis.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Drinking water exposures are not impacted by the new uses, and thus have not changed since the last assessment in the May 5, 2016 rulemaking.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the May 5, 2016 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD: They are 14% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: They are 75% of the cPAD for all infants less than 1 year old, the population subgroup with the highest exposure estimate. The short-

term MOE is greater than the Agency's level of concern of 100: It is 1100 for adults and 400 for children.

Intermediate-term or long-term residential exposures are not expected.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fluxapyroxad residues. More detailed information about the Agency's analysis can be found at <http://www.regulations.gov> in the document titled "Fluxapyroxad. Human Health Risk Assessment for a Proposed Use of Fluxapyroxad on Pomegranate, Crop Group Expansion for Cottonseed Subgroup 20C and Crop Group Conversions for Vegetable, Fruiting, Group 8–10 and Fruit, Pome, and Group 11–10" in docket ID number EPA-HQ-OPP-2020-0228.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate residue analytical method is available for the purpose of tolerance enforcement. Liquid chromatography–mass spectrometry LC/MS/MS BASF Method L0137/01, previously deemed acceptable as an enforcement method for plant matrices, is applicable for the analysis of fluxapyroxad residues.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

Codex does not have an MRL for fluxapyroxad in/on pomegranate. For the cottonseed crop subgroup 20C, the 0.5 ppm tolerance is harmonized with the Codex MRL. The Agency is not harmonizing with the Codex pome fruit (group 11–10) MRL of 0.9 ppm because the petitioner requested that the tolerance remain at 0.8 ppm in order to harmonize with Canada and other key exporting countries. EPA also concludes that harmonization with the Codex fruiting vegetable (group 8–10) MRL of 0.6 ppm is not appropriate as it could result in violative residues despite application consistent with approved label rates. The Codex fruiting vegetable MRL is based on a 7-day pre-harvest interval (PHI), not a 0-day PHI as currently registered in the United States.

C. Revisions to Petitioned-For Tolerances

The tolerance for the cottonseed subgroup 20C is being established at 0.5 ppm rather than 0.3 ppm as requested in order to harmonize with Codex.

V. Conclusion

Therefore, tolerances are established for residues of fluxapyroxad in or on the Cottonseed subgroup 20C at 0.5 ppm; Fruit, pome, group 11–10 at 0.8 ppm; Pomegranate at 0.2 ppm; and Vegetable, fruiting, group 8–10 at 0.7 ppm. Additionally, the existing tolerances for Cotton, undelinted seed; Fruit, pome, group 11; and Vegetables, fruiting, group 8 are removed since they are superseded by the new tolerances established in today's action.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances and modifications in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress

in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 6, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.666, paragraph (a):

■ i. Add a heading to the table;

- ii. Remove the entry for "Cotton, undelinted seed";
- iii. Add an entry for "Cottonseed, subgroup 20C" in alphabetical order;
- iv. Remove the entry for "Fruit, pome, group 11";
- v. Add entries for "Fruit, pome, group 11–10" and "Pomegranate" in alphabetical order;
- vi. Remove the entry for "Vegetables, fruiting group 8"; and
- vii. Add an entry for "Vegetable, fruiting, group 8–10" in alphabetical order.

The additions read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	*
Cottonseed, subgroup 20C	0.5
* * * * *	*
Fruit, pome, group 11–10	0.8
* * * * *	*
Pomegranate	0.2
* * * * *	*
Vegetable, fruiting, group 8–10 ..	0.7
* * * * *	*
* * * * *	*

[FR Doc. 2021–14708 Filed 7–12–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RTID 0648–XB145

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; inseason General category retention limit adjustment.

SUMMARY: NMFS is adjusting the Atlantic bluefin tuna (BFT) General category daily retention limit from three large medium or giant BFT to one large medium or giant BFT for the remainder

of the June through August 2021 subquota period. This action is based on consideration of the regulatory determination criteria regarding inseason adjustments and applies to Atlantic Tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective July 11, 2021 through August 31, 2021.

FOR FURTHER INFORMATION CONTACT:

Larry Redd, Jr., larry.redd@noaa.gov, 301–427–8503, Nicholas Velseboer, nicholas.velseboer@noaa.gov, 978–675–2168, or Lauren Latchford, lauren.latchford@noaa.gov, 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

In 2018, NMFS implemented a final rule that established the U.S. BFT quota and subquotas consistent with ICCAT Recommendation 17–06 (83 FR 51391, October 11, 2018). In 2020, following a stock assessment update, ICCAT adopted Recommendation 20–06, which maintained the total allowable catch of 2,350 metric tons (mt) and the associated U.S. quota. As such, as described in § 635.27(a), the current baseline U.S. quota continues to be 1,247.86 mt (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). The baseline quota for the General category is 555.7 mt. Each of the General category time periods (January, June through

August, September, October through November, and December) is allocated a portion of the annual General category quota. This action would adjust the daily retention limit for the remainder of the second time period in 2021, June through August.

Adjustment of General Category Daily Retention Limit

The default General category retention limit is one large medium or giant BFT (measuring 73 inches (185 cm) curved fork length (CFL) or greater) per vessel per day/trip (§ 635.23(a)(2)).

Under § 635.23(a)(4), NMFS may increase or decrease the daily retention limit of large medium and giant BFT over a range of zero to a maximum of five per vessel based on consideration of the relevant criteria provided under § 635.27(a)(8). NMFS adjusted the daily retention limit for the beginning of the June through August 2021 subquota period from the default level of one large medium or giant BFT to three large medium or giant BFT (86 FR 25992, May 12, 2021). NMFS has considered the relevant determination criteria and their applicability to the General category BFT retention limit for the remainder of the June through August 2021 subquota time period. The criteria include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by General category fishermen and provided by BFT dealers continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Prolonged opportunities to land BFT over the longest time-period allowable would support the collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the General category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). Commercial-size BFT are currently readily available to vessels fishing under the General category quota. As of July 8, 2021, the General category has landed approximately 34.9 mt, representing 13 percent of the General category subquota for the June 1 through August 31 period. If current catch rates continue with the three-fish daily limit, the available subquota for June 1 through August 31 period will be reached or exceeded, and NMFS would

need to close the fishery earlier than otherwise would be necessary under a lower limit. NMFS intends to provide General category participants in all areas and time periods opportunities to harvest the General category quota without exceeding it, through active inseason management such as retention limit adjustments and/or the timing and amount of quota transfers (based on consideration of the determination criteria regarding inseason adjustments), while extending the season as long as practicable. NMFS is setting the limit for the remainder of the June through August 2021 subquota period in such a way that NMFS believes, informed by past experience, increases the likelihood that the fishery will remain open throughout the subperiod and year. NMFS also took into consideration a recently published proposed rule that would set restricted-fishing days for the General category during the months of July through November 2021 (86 FR 25992, May 12, 2021). If finalized, that proposed rule would further increase the likelihood that the fishery would remain open throughout the subperiod and year.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the adjustment on accomplishing the objectives of the 2006 Consolidated HMS FMP (§ 635.27(a)(8)(v) and (vi)). This retention limit would be consistent with established quotas and subquotas, which are implemented consistent with ICCAT recommendations, (established in Recommendation 17–06 and maintained in Recommendation 20–06), ATCA, and the objectives of the 2006 Consolidated HMS FMP and amendments. In establishing these quotas and subquotas and associated management measures, ICCAT and NMFS considered the best scientific information available, objectives for stock management and status, and effects on the stock. This retention limit is in line with the established management measures and stock status determinations. It is also important that NMFS limit landings to the subquotas both to adhere to the subquota allocations and to ensure that landings are as consistent as possible with the pattern of fishing mortality (*e.g.*, fish caught at each age) that was assumed in the latest stock assessment, and this retention limit is consistent with those objectives.

Another principal consideration in setting the retention limit is the objective of providing opportunities to harvest the available General category quota without exceeding the annual quota, based on the objectives of the

2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest available BFT quota allocations (related to § 635.27(a)(8)(x)).

Given these considerations, NMFS has determined that a one-fish General category retention limit is warranted for the remainder of the June-August 2021 subquota period. This retention limit would provide a reasonable opportunity to harvest the available U.S. BFT quota (including the expected increase in available 2021 quota based on 2020 underharvest), without exceeding it, while maintaining an equitable distribution of fishing opportunities; help optimize the ability of the General category to harvest its available quota; allow collection of a broad range of data for stock monitoring purposes; and be consistent with the objectives of the 2006 Consolidated HMS FMP and amendments. Therefore, NMFS decreases the General category retention limit from three to one large medium or giant BFT per vessel per day/trip, effective July 11, 2021, through August 31, 2021.

Regardless of the duration of a fishing trip, the daily retention limit applies upon landing. For example (and specific to the June through August 2021 limit), whether a vessel fishing under the General category retention limit takes a two-day trip or makes two trips in one day, the daily limit of one fish may not be exceeded upon landing. This General category retention limit is effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeting fishing for BFT, and applies to vessels permitted in the General category, as well as to HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT. For information regarding the HMS Charter/Headboat commercial sale endorsement, see 82 FR 57543, December 6, 2017.

Monitoring and Reporting

NMFS will actively monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustments, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat vessel owners are required to report their own catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each

trip, by accessing hmspermits.noaa.gov or by using the HMS Catch Reporting app, or calling (888) 872-8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281-9260, or access hmspermits.noaa.gov, for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 635, which was issued pursuant to section 304(c), and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

NMFS provides notification of retention limit adjustments by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line and on hmspermits.noaa.gov. The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery.

Prior notice and an opportunity for public comment is impracticable because the regulations implementing the 2006 Consolidated HMS FMP, as amended, intended that inseason retention limit adjustments would allow the agency to respond quickly to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Based on available BFT quotas, fishery performance in recent years, and the availability of BFT on the fishing grounds, adjustment to the General category BFT daily retention limit from the current level is warranted.

Delays in adjusting the retention limit may result in the available June 1 through August 31 subquota being reached or exceeded and NMFS needing to close the fishery earlier than otherwise would be necessary under the lower limit being set for the remainder of this period. Such delays could adversely affect those General category and HMS Charter/Headboat vessels that would otherwise have an opportunity to harvest BFT if the fishery were to remain open for as feasible throughout the remaining subquota periods. Limited opportunities to harvest the respective quotas may have negative social and economic impacts for U.S. fishermen that depend upon catching the available quota within the time periods designated in the 2006 Consolidated HMS FMP and amendments. Adjustment of the retention limit needs to be effective as soon as possible to extend fishing opportunities for fishermen in all geographic areas, and to provide equitable opportunities.

Prior notice and an opportunity for public comment is also impracticable for the retention limit adjustment to one fish for the remainder of the June through August 2021 subquota period. Avoiding delay in implementation will also allow fishermen to take advantage of the availability of fish on the fishing grounds and of quota. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For these reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: July 8, 2021.

Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2021-14849 Filed 7-8-21; 4:15 pm]
BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 201209-0332; RTID 0648-XB229]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer from VA to NY

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; quota transfer.

SUMMARY: NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2021 commercial bluefish quota to the State of New York. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for Virginia and New York.

DATES: Effective July 12, 2021 through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, (978) 281-9225.

SUPPLEMENTARY INFORMATION:

Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2021 allocations were published on December 16, 2020 (85 FR 81421).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan (FMP) published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must approve any such transfer based on the criteria in § 648.162(e). In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether: The transfer or combinations would preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

Virginia is transferring 50,000 lb (22,680 kg) of bluefish commercial quota to New York through mutual agreement of the states. This transfer was requested to ensure that New York would not exceed its 2021 state quota. The revised bluefish quotas for 2021 are: Virginia, 278,800 lb (126,099 kg); and New York, 337,438 lb (153,059 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was

issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

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

Dated: July 8, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021-14842 Filed 7-12-21; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 86, No. 131

Tuesday, July 13, 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.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 12

[EPA–R03–OAR–2021–0358; FRL–8686–01–R3]

Air Plan Approval; Pennsylvania; 1997 8-Hour Ozone National Ambient Air Quality Standards Second Maintenance Plan for the Greene County Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania. This revision pertains to the Commonwealth's plan, submitted by the Pennsylvania Department of Environmental Protection (PADEP), for maintaining the 1997 8-hour ozone national ambient air quality standard (NAAQS) (referred to as the "1997 ozone NAAQS") in the Greene County, Pennsylvania area (Greene County Area). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before August 12, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2021–0358 at <https://www.regulations.gov>, or via email to gordon.mike@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the

official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (e.g., on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Adam Yarina, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103. The telephone number is (215) 814–2108. Mr. Yarina can also be reached via electronic mail at yarina.adam@epa.gov.

SUPPLEMENTARY INFORMATION: On February 25, 2020, PADEP submitted a revision to the Pennsylvania SIP to incorporate a plan for maintaining the 1997 ozone NAAQS in the Greene County Area through April 20, 2029, in accordance with CAA section 175A.

I. Background

In 1979, under section 109 of the CAA, EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), averaged over a 1-hour period. 44 FR 8202 (February 8, 1979). On July 18, 1997 (62 FR 38856),¹ EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. EPA set the 1997 ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set.

Following promulgation of a new or revised NAAQS, EPA is required by the

CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. On April 30, 2004 (69 FR 23857), EPA designated the Greene County Area as nonattainment for the 1997 ozone NAAQS, effective June 15, 2004. The Greene County Area consists solely of Greene County in Pennsylvania.

Once a nonattainment area has three years of complete and certified air quality data that has been determined to attain the NAAQS, and the area has met the other criteria outlined in CAA section 107(d)(3)(E),² the state can submit a request to EPA to redesignate the area to attainment. Areas that have been redesignated by EPA from nonattainment to attainment are referred to as "maintenance areas." One of the criteria for redesignation is to have an approved maintenance plan under CAA section 175A. The maintenance plan must demonstrate that the area will continue to maintain the standard for the period extending 10 years after redesignation, and it must contain such additional measures as necessary to ensure maintenance as well as contingency measures as necessary to assure that violations of the standard will be promptly corrected.

On March 19, 2009 (74 FR 11671, effective April 20, 2009), EPA approved a redesignation request and maintenance plan from PADEP for the Greene County Area. In accordance with CAA section 175A(b), at the end of the eighth year after the effective date of the redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the standard for an additional 10 years.

EPA's final implementation rule for the 2008 ozone NAAQS revoked the 1997 ozone NAAQS and provided that one consequence of revocation was that areas that had been redesignated to attainment (i.e., maintenance areas) for the 1997 ozone NAAQS no longer needed to submit second 10-year maintenance plans under CAA section

¹ In March 2008, EPA completed another review of the primary and secondary ozone standards and tightened them further by lowering the level for both to 0.075 ppm. 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone standards and tightened them by lowering the level for both to 0.70 ppm. 80 FR 65292 (October 26, 2015).

² The requirements of CAA section 107(d)(3)(E) include attainment of the NAAQS, full approval under section 110(k) of the applicable SIP, determination that improvement in air quality is a result of permanent and enforceable reductions in emissions, demonstration that the state has met all applicable section 110 and part D requirements, and a fully approved maintenance plan under CAA section 175A.

175A(b).³ However, in *South Coast Air Quality Management District v. EPA*⁴ (South Coast II), the United States Court of Appeals for the District of Columbia (D.C. Circuit) vacated EPA's interpretation that, because of the revocation of the 1997 ozone standard, second maintenance plans were not required for "orphan maintenance areas," (*i.e.*, areas like the Greene County Area) that had been redesignated to attainment for the 1997 ozone NAAQS and were designated attainment for the 2008 ozone NAAQS. Thus, states with these "orphan maintenance areas" under the 1997 ozone NAAQS must submit maintenance plans for the second maintenance period.

As previously discussed, CAA section 175A sets forth the criteria for adequate maintenance plans. In addition, EPA has published longstanding guidance that provides further insight on the content of an approvable maintenance plan, explaining that a maintenance plan should address five elements: (1) An attainment emissions inventory; (2) a maintenance demonstration; (3) a commitment for continued air quality monitoring; (4) a process for verification of continued attainment; and (5) a contingency plan. The 1992 Calcagni Memo⁵ provides that states may generally demonstrate maintenance by either performing air quality modeling to show that the future mix of sources and emission rates will not cause a violation of the NAAQS or by showing that future emissions of a pollutant and its precursors will not exceed the level of emissions during a year when the area was attaining the NAAQS (*i.e.*, attainment year inventory). See 1992 Calcagni Memo at p. 9. EPA further clarified in three subsequent guidance memos describing "limited maintenance plans" (LMPs)⁶ that the requirements of CAA section 175A could be met by demonstrating that the area's design value⁷ was well below the NAAQS and

that the historical stability of the area's air quality levels showed that the area was unlikely to violate the NAAQS in the future. Specifically, EPA believes that if the most recent air quality design value for the area is at a level that is below 85% of the standard, or in this case below 0.071 ppm, then EPA considers the state to have met the section 175A requirement for a demonstration that the area will maintain the NAAQS for the requisite period. Accordingly, on February 25, 2020, PADEP submitted an LMP for the Greene County Area, following EPA's LMP guidance and demonstrating that the area will maintain the 1997 ozone NAAQS through April 20, 2029, *i.e.*, through the entire 20-year maintenance period.

After PADEP's submittal of this LMP, it was determined that the most current certified design value period (2017–2019) was invalid due to incomplete data. PADEP operates and maintains one ozone monitor at the Holbrook ambient air monitoring station (AQ5 ID 42–059–0002) in Greene County, PA. During the 2018 and 2019 ozone monitoring seasons, the Holbrook ambient air monitoring station had missing ozone data for 35 and 39 days, respectively. The Holbrook ozone data was missing for a total of 74 days in the two-year span because of several reasons, including power outages and quality assurance criteria not being met. As a result of the frequency of missing data, the total valid ozone data capture at the Holbrook monitoring site was 86% in 2018 and 84% in 2019. With an ozone data capture of 93% in 2017, the three-year (2017–2019) average was 88%. According to 40 CFR part 50 appendix P, section 2.3(b), three consecutive years of ambient air ozone data with data availability of at least 90% of the days within the ozone monitoring season, on average, are required, with a minimum data completeness in any one year of at least 75% within the ozone monitoring season. Since the 2019 ozone design value average data completeness was 88%, it did not meet the 90% criteria outlined in 40 CFR part 50 appendix P, section 2.3(b).

PADEP submitted a data completeness substitution analysis for the Holbrook monitor on March 3, 2021, which included data substitutions for 41 of the missing days. The data substitution methodology relied on meteorological data, historical records for the Holbrook ozone monitoring site

and surrounding monitoring sites, and daily maximum regional ozone monitoring values for the 2015–2019 period. PADEP used a conservative approach of replacing the missing data at Holbrook in 2018 and 2019 with the regional maximum 8-hour ozone concentration and calculated updated design values for the 2017–2019 period. EPA analyzed PADEP's submittal and found it acceptable and provided PADEP with Regional Administrator review and approval as required by Appendix I on March 24, 2021. PADEP's data substitution brings the data capture rate to 90% for 2018, 91% for 2019, and 91% for the 2017–2019 design value, which meets the requirements of 40 CFR part 50 appendix P, section 2.3(b). For more information on PADEP's data substitution analysis, including PADEP's methodology, raw data, and design value calculations, as well as EPA's review and approval, please see the rulemaking docket.⁸

II. Summary of SIP Revision and EPA Analysis

PADEP's February 25, 2020 SIP submittal outlines a plan for continued maintenance of the 1997 ozone NAAQS which addresses the criteria set forth in the 1992 Calcagni Memo as follows.

A. Attainment Emissions Inventory

For maintenance plans, a state should develop a comprehensive and accurate inventory of actual emissions for an attainment year which identifies the level of emissions in the area which is sufficient to maintain the NAAQS. The inventory should be developed consistent with EPA's most recent guidance. For ozone, the inventory should be based on typical summer day's emissions of oxides of nitrogen (NO_x) and volatile organic compounds (VOC), the precursors to ozone formation. In the first maintenance plan for the Greene County Area, PADEP used 2004 for the attainment year inventory because 2004 was one of the years in the 2003–2005 three-year period when the area first attained the 1997 ozone NAAQS.⁹ The Greene County Area continued to monitor attainment of the 1997 ozone NAAQS in 2014. Therefore, the emissions inventory from 2014 represents

³ See 80 FR 12315 (March 6, 2015).

⁴ 882 F.3d 1138 (D.C. Cir. 2018).

⁵ "Procedures for Processing Requests to Redesignate Areas to Attainment," Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (1992 Calcagni Memo).

⁶ See "Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas" from Sally L. Shaver, Office of Air Quality Planning and Standards (OAQPS), dated November 16, 1994; "Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas" from Joseph Paisie, OAQPS, dated October 6, 1995; and "Limited Maintenance Plan Option for Moderate PM₁₀ Nonattainment Areas" from Lydia Wegman, OAQPS, dated August 9, 2001.

⁷ The ozone design value for a monitoring site is the 3-year average of the annual fourth-highest daily maximum

8-hour average ozone concentrations. The design value for an ozone nonattainment area is the highest design value of any monitoring site in the area.

⁸ Specifically, the documents labeled "PADEP Transmittal Letter Greene County SIP," "EPA RA Approval Letter for PADEP Holbrook Missing Ozone Data Analysis," "EPA Holbrook 2017–2019 Design Value Report," and "EPA Holbrook 2018–2019 Raw Data Qualifier Report" in Docket ID # EPA–R03–OAR–2021–0358.

⁹ For more information, see EPA's July 16, 2008 notice proposing to redesignate the Greene County Area to attainment for the 1997 ozone NAAQS (73 FR 40813).

emissions levels conducive to continued attainment (*i.e.*, maintenance) of the NAAQS. Thus, PADEP is using 2014 as representing attainment level emissions for its second maintenance plan. Pennsylvania used 2014 summer day emissions from EPA's 2014 version 7.0 modeling platform as the basis for the 2014 inventory presented in Table 1.¹⁰

TABLE 1—2014 TYPICAL SUMMER DAY NO_x AND VOC EMISSIONS FOR THE GREENE COUNTY AREA
[tons/day]

Source category	NO _x emis- sions	VOC emis- sions
Point	0.52	0.69
Nonpoint	8.55	10.89
Onroad	3.30	1.08
Nonroad	1.45	0.59

The data shown in Table 1 is based on the 2014 National Emissions Inventory (NEI) version 2.¹¹ The inventory addresses four anthropogenic emission source categories: Stationary (point) sources, stationary nonpoint (area) sources, nonroad mobile, and onroad mobile sources. Point sources are stationary sources that have the potential to emit (PTE) more than 100 tons per year (tpy) of VOC, or more than 50 tpy of NO_x, and which are required to obtain an operating permit. Data are collected for each source at a facility and reported to PADEP. Examples of point sources include kraft mills, electrical generating units (EGUs), and pharmaceutical factories. Nonpoint sources include emissions from equipment, operations, and activities that are numerous and in total have significant emissions. Examples include emissions from commercial and consumer products, portable fuel containers, home heating, repair and refinishing operations, and crematories. The onroad emissions sector includes emissions from engines used primarily to propel equipment on highways and other roads, including passenger vehicles, motorcycles, and heavy-duty diesel trucks. The nonroad emissions

sector includes emissions from engines that are not primarily used to propel transportation equipment, such as generators, forklifts, and marine pleasure craft. EPA reviewed the emissions inventory submitted by PADEP and proposes to conclude that the plan's inventory is acceptable for the purposes of a subsequent maintenance plan under CAA section 175A(b).

B. Maintenance Demonstration

To attain the 1997 ozone NAAQS, the three-year average of the fourth-highest daily average ozone concentrations (design value, or "DV") at each monitor within an area must not exceed 0.08 ppm. Based on the rounding convention described in 40 CFR part 50, appendix I, the standard is attained if the DV is 0.084 or below. CAA section 175A requires a demonstration that the area will continue to maintain the NAAQS throughout the duration of the requisite maintenance period. Consistent with the prior guidance documents discussed previously in this document as well as EPA's November 20, 2018 "Resource Document for 1997 Ozone NAAQS Areas: Supporting Information for States Developing Maintenance Plans" (2018 Resource Document),¹² EPA believes that if the most recent DV for the area

is well below the NAAQS (*i.e.*, below 85%, or in this case below 0.071 ppm), the section 175A demonstration requirement has been met, provided that Prevention of Significant Deterioration (PSD) requirements, any control measures already in the SIP, and any Federal measures remain in place through the end of the second 10-year maintenance period (absent a showing consistent with section 110(l) that such measures are not necessary to assure maintenance).

For the purposes of demonstrating continued maintenance with the 1997 ozone NAAQS, PADEP provided 3-year DVs at the monitor located in the Greene County Area from 2007 to 2018. This includes DVs for 2005–2007, 2006–2008, 2007–2009, 2008–2010, 2009–2011, 2010–2012, 2011–2013, 2012–2014, 2013–2015, 2014–2016, 2015–2017, and 2016–2018, which are shown in Table 2.¹³ In addition, EPA has reviewed the most recent ambient air quality monitoring data for ozone in the Greene County Area, as submitted by Pennsylvania and recorded in EPA's Air Quality System (AQS). The most recent DVs (*i.e.*, 2017–2019) at monitors located in the Greene County Area are also shown in Table 2.¹⁴

TABLE 2—1997 OZONE NAAQS DESIGN VALUES (PPM) FOR THE GREENE COUNTY AREA

County	AQS Site ID	2005– 2007	2006– 2008	2007– 2009	2008– 2010	2009– 2011	2010– 2012	2011– 2013	2012– 2014	2013– 2015	2014– 2016	2015– 2017	2016– 2018	2017– 2019
Greene	42–059–0002	.08	.076	.072	.072	.069	.071	.067	.068	.067	.067	.068	.066	.063

The data in Table 2 show that the DVs for the Greene County Area have been

below 85% of the 1997 ozone NAAQS (*i.e.*, less than or equal to 0.071 ppm)

since the 2009–2011 period. The highest DV for the 2017–2019 period at the

¹⁰ For more information, visit https://www.epa.gov/sites/production/files/2018-11/ozone_1997_naaqs_emiss_inv_data_nov_19_2018_0.xlsx.

¹¹ The NEI is a comprehensive and detailed estimate of air emissions of criteria pollutants, criteria precursors, and hazardous air pollutants from air emissions sources. The NEI is released every three years based primarily upon data provided by State, Local, and Tribal air agencies for sources in their jurisdictions and supplemented by data developed by EPA.

¹² This resource document is included in the docket for this rulemaking available online at <https://www.regulations.gov>, Docket ID: EPA–R03–OAR–2020–0316 and is also available at https://www.epa.gov/sites/production/files/2018-11/documents/ozone_1997_naaqs_lmp_resource_document_nov_20_2018.pdf.

¹³ See also Table II–2 of PADEP's February 25, 2020 submittal, included in the docket for this rulemaking available online at <https://www.regulations.gov>, Docket ID: EPA–R03–OAR–2021–0358.

¹⁴ This data is also included in the docket for this rulemaking available online at <https://www.regulations.gov>, Docket ID: EPA–R03–OAR–2021–0358 and is also available at <https://www.epa.gov/air-trends/air-quality-design-values#report>.

monitor in the Greene County Area is 0.064 ppm, which is well below 85% of the 1997 ozone NAAQS.

States can also support the demonstration of continued maintenance by showing stable or improving air quality trends, and according to EPA's 2018 Resource Document, several kinds of analyses can be performed by states wishing to make such a showing. One approach is to take the most recent DV at a monitor located in the area and add the maximum DV increase over one or more consecutive years that has been observed in the area over the past several years. A sum of these two values that does not exceed the level of the 1997 ozone NAAQS may be a good indicator of expected continued attainment. The data in Table 2 of this document show that the largest DV increase at the monitor located in the Greene County Area was 0.002 ppm, which occurred between the 2009–2011 (0.069 ppm) and 2010–2012 (0.071 ppm) DVs. Adding 0.002 ppm to the DV for the 2017–2019 period (0.064 ppm) results in 0.066 ppm, a sum that is still below the 1997 ozone NAAQS.

The Greene County Area has maintained air quality levels below the 1997 ozone NAAQS since the Area first attained the NAAQS in 2009, and maintained air quality levels at or below 85% of the NAAQS since 2011.¹⁵ Additional supporting information that the area is expected to continue to maintain the standard can be found in projections of future year DVs that EPA recently completed to assist states with the development of interstate transport SIPs for the 2015 8-hour ozone NAAQS. Those projections, made for the year 2023, show that the DV at the monitor located in the Greene County Area is expected to be 0.0565 ppm.¹⁶ Therefore, EPA proposes to determine that future violations of the 1997 ozone NAAQS in the Greene County Area are unlikely.

C. Continued Air Quality Monitoring and Verification of Continued Attainment

Once an area has been redesignated to attainment, the state remains obligated to maintain an air quality network in accordance with 40 CFR part 58 to verify the area's attainment status. In the

February 25, 2020 submittal, PADEP commits to continue to operate their air monitoring network in accordance with 40 CFR part 58. PADEP also commits to track the attainment status of the Greene County Area for the 1997 ozone NAAQS through the review of air quality and emissions data during the second maintenance period. This includes an annual evaluation of vehicles miles traveled (VMT) and stationary source emissions data compared to the assumptions included in the LMP. PADEP also states that it will evaluate the periodic (*i.e.*, every three years) emission inventories prepared under EPA's Air Emission Reporting Requirements (40 CFR part 51, subpart A). Based on these evaluations, PADEP will consider whether any further emission control measures should be implemented for the Greene County Area. EPA has analyzed the commitments in PADEP's submittal and is proposing to determine that they meet the requirements for continued air quality monitoring and verification of continued attainment.

D. Contingency Plan

The contingency plan provisions are designed to promptly correct or prevent a violation of the NAAQS that might occur after redesignation of an area to attainment. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to assure that the state will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the contingency measures to be adopted, a schedule and procedure for adoption and implementation of the contingency measures, and a time limit for action by the state. The state should also identify specific indicators to be used to determine when the contingency measures need to be adopted and implemented. The maintenance plan must require that the state will implement all pollution control measures that were contained in the SIP before redesignation of the area to attainment. See section 175(A)(d) of the CAA.

PADEP's February 25, 2020 submittal includes a contingency plan for the Greene County Area. In the event that the fourth highest eight-hour ozone concentrations at a monitor in the Greene County Area exceeds 84 parts per billion (ppb) (equivalent to 0.084 ppm) for two consecutive years, but prior to an actual violation of the NAAQS, PADEP will evaluate whether additional local emission control measures should be implemented that may prevent a violation of the NAAQS.¹⁷ After analyzing the conditions causing the excessive ozone levels, evaluating the effectiveness of potential corrective measures, and considering the potential effects of Federal, state, and local measures that have been adopted but not yet implemented, PADEP will begin the process of implementing selected measures so that they can be enacted as expeditiously as practicable following a violation of the NAAQS. In the event of a violation, PADEP commits to adopting additional emission reduction measures as expeditiously as practicable in accordance with the schedule included in the contingency plan as well as the CAA and applicable Pennsylvania statutory requirements.

PADEP will use the following criteria when considering additional emission reduction measures to adopt to address a violation of the 1997 ozone NAAQS in the Greene County Area: (1) Air quality analysis indicating the nature of the violation, including the cause, location, and source; (2) emission reduction potential, including extent to which emission generating sources occur in the nonattainment area; (3) timeliness of implementation in terms of the potential to return the area to attainment as expeditiously as practicable; and (4) costs, equity, and cost-effectiveness. The measures PADEP would consider pursuing for adoption in the Greene County Area include, but are not limited to, those summarized in Table 3. If additional emission reductions are necessary, PADEP commits to adopt additional emission reduction measures to attain and maintain the 1997 ozone NAAQS.

TABLE 3—GREENE COUNTY AREA SECOND MAINTENANCE PLAN CONTINGENCY MEASURES

Non-Regulatory Measures

- Voluntary diesel engine “chip reflash” (installation software to correct the defeat device option on certain heavy-duty diesel engines).
- Diesel retrofit (including replacement, repowering or alternative fuel use) for public or private local onroad or offroad fleets.

¹⁵ As explained in EPA's July 16, 2008 notice proposing to redesignate the Greene County Area as attainment for the 1997 ozone NAAQS (73 FR 40813), the 2003–2005 DV for the Greene County Area was 0.081 ppm.

¹⁶ See U.S. EPA, “Air Quality Modeling Technical Support Document for the Updated 2023 Projected Ozone Design Values,” Office of Air Quality Planning and Standards, dated June 2018, available at [https://www.epa.gov/airmarkets/air-quality-](https://www.epa.gov/airmarkets/air-quality-modeling-technical-support-document-updated-2023-projected-ozone-design)

[modeling-technical-support-document-updated-2023-projected-ozone-design](https://www.epa.gov/airmarkets/air-quality-modeling-technical-support-document-updated-2023-projected-ozone-design).

¹⁷ A violation of the NAAQS occurs when an area's 3-year design value exceeds the NAAQS.

TABLE 3—GREENE COUNTY AREA SECOND MAINTENANCE PLAN CONTINGENCY MEASURES—Continued

Idling reduction technology for Class 2 yard locomotives.
Idling reduction technologies or strategies for truck stops, warehouses, and other freight-handling facilities.
Accelerated turnover of lawn and garden equipment, especially commercial equipment, including promotion of electric equipment.
Additional promotion of alternative fuel (e.g., biodiesel) for home heating and agricultural use.
Regulatory Measures ¹⁸
Additional control on consumer products. ¹⁹
Additional controls on portable fuel containers. ²⁰

The contingency plan includes schedules for the adoption and implementation of both non-regulatory and regulatory contingency measures, which are summarized in Tables 4 and 5, respectively.

TABLE 4—IMPLEMENTATION SCHEDULE FOR GREENE COUNTY AREA NON-REGULATORY CONTINGENCY MEASURES

Time after triggering event	Action
Within 2 months	PADEP will identify stakeholders for potential non-regulatory measures for further development.
Within 3 months	If funding is necessary, PADEP will identify potential sources of funding and the timeframe for when funds would be available.
Within 9 months	If state loans or grants are required, PADEP will enter into agreements with implementing organizations. PADEP will also quantify projected emission benefits.
Within 12 months	PADEP will submit revised SIP to EPA.
Within 12–24 months	PADEP will implement strategies and projects.

TABLE 5— IMPLEMENTATION SCHEDULE FOR GREENE AREA REGULATORY CONTINGENCY MEASURES

Time after triggering event	Action
Within 1 month	PADEP will submit request to begin regulatory development process.
Within 3 months	Request will be reviewed by the Air Quality Technical Advisory Committee (AQTAC), Citizens Advisory Council, and other advisory committees as appropriate.
Within 6 months	Environmental Quality Board (EQB) meeting/action.
Within 8 months	PADEP will publish regulatory measure in the Pennsylvania Bulletin for comment as proposed rulemaking.
Within 10 months	PADEP will hold a public hearing and comment period on proposed rulemaking.
Within 11 months	House and Senate Standing Committee and Independent Regulatory Review Commission (IRCC) comment on proposed rulemaking.
Within 13 months	AQTAC, Citizens Advisory Council, and other committees will review responses to comment(s), if applicable, and the draft final rule.
Within 16 months	EQB meeting/action.
Within 17 months	The IRCC will take action on final rule
Within 18 months	Attorney General's review/action.
Within 19 months	PADEP will publish the regulatory measure as a final rule in the Pennsylvania Bulletin and submit to EPA as a SIP revision. The regulation will become effective upon publication in the Pennsylvania Bulletin.

EPA proposes to find that the contingency plan included in PADEP's February 25, 2020 submittal satisfies the pertinent requirements of CAA section 175A(d). EPA notes that while five of the potential contingency measures included in the Commonwealth's second maintenance plan are non-regulatory, their inclusion among other measures is overall SIP-strengthening, and their inclusion does not alter EPA's proposal to find the LMP is fully approvable. EPA also finds that the submittal acknowledges Pennsylvania's

continuing requirement to implement all pollution control measures that were contained in the SIP before redesignation of the Greene County Area to attainment.

E. Transportation Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS (CAA

176(c)(1)(B)). EPA's conformity rule at 40 CFR part 93 requires that transportation plans, programs and projects conform to SIPs and establish the criteria and procedures for determining whether they conform. The conformity rule generally requires a demonstration that emissions from the Regional Transportation Plan (RTP) and Transportation Improvement Program (TIP) are consistent with the motor vehicle emissions budget (MVEB) contained in the control strategy SIP revision or maintenance plan (40 CFR

¹⁸ These regulatory measures were considered potential cost-effective and timely control strategies by the Ozone Transport Commission (OTC) as well as the Mid-Atlantic Regional Air Management Association and the Mid-Atlantic/Northeast Visibility Union. The OTC is a multi-state organization responsible for developing regional solutions to ground-level ozone pollution in the Northeast and Mid-Atlantic, including the development of model rules that member states may

adopt. OTC member states include: Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Virginia. For more information on the OTC, visit <https://otcair.org/index.asp>. To view the model rules developed by the OTC, including those for consumer products and portable fuel containers, visit <https://otcair.org/document.asp?view=modelrules>.

¹⁹ Pennsylvania's existing controls on consumer products are under 25 Pa. Code Chapter 130, Subchapters B and C (38 Pa.B. 5598). This contingency measure includes the adoption of additional controls on consumer products such as VOC limits for adhesive removers.

²⁰ Existing controls on portable fuel containers can be found under 40 CFR part 59, subpart F—Control of Evaporative Emissions From New and In-Use Portable Fuel Containers.

93.101, 93.118, and 93.124). An MVEB is defined as “that portion of the total allowable emissions defined in the submitted or approved control strategy implementation plan revision or maintenance plan for a certain date for the purpose of meeting reasonable further progress milestones or demonstrating attainment or maintenance of the NAAQS, for any criteria pollutant or its precursors, allocated to highway and transit vehicle use and emissions (40 CFR 93.101).”

Under the conformity rule, LMP areas may demonstrate conformity without a regional emission analysis (40 CFR 93.109(e)). However, because LMP areas are still maintenance areas, certain aspects of transportation conformity determinations still will be required for transportation plans, programs, and projects. Specifically, for such determination, RTPs, TIPs, and transportation projects still will have to demonstrate that they are fiscally constrained (40 CFR 93.108), meet the criteria for consultation (40 CFR 93.105 and 93.112) and transportation control measure implementation in the conformity rule provisions (40 CFR 93.113). Additionally, conformity determinations for RTPs and TIPs must be determined no less frequently than every four years, and conformity of plan and TIP amendments and transportation projects is demonstrated in accordance with the timing requirements specified in 40 CFR 93.104. In addition, for projects to be approved, they must come from a currently conforming RTP and TIP (40 CFR 93.114 and 93.115). The Greene County Area remains under the obligation to meet the applicable conformity requirements for the 1997 ozone NAAQS.

III. Proposed Action

EPA’s review of PADEP’s February 25, 2020 submittal indicates that it meets all applicable CAA requirements, specifically the requirements of section 175A. EPA is proposing to approve the second maintenance plan for the Greene County Area as a revision to the Pennsylvania SIP. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions EPA’s role is to approve state choices if

they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rulemaking, proposing approval of Pennsylvania’s second maintenance plan for the Greene County Area, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Volatile organic compounds.

Dated: July 7, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

[FR Doc. 2021–14853 Filed 7–12–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2020–0062; FF09E21000 FXES11110900000 212]

RIN 1018–BE55

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Pearl Darter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the pearl darter (*Percina aurora*) under the Endangered Species Act of 1973 (Act), as amended. In total, approximately 517 river miles (832 river kilometers) in Clarke, Covington, Forrest, George, Greene, Lauderdale, Jackson, Jones, Newton, Perry, Simpson, Stone, and Wayne Counties, Mississippi, fall within the boundaries of the proposed critical habitat designation. If we finalize this rule as proposed, it would extend the Act’s protections to this species’ critical habitat. We also announce the availability of a draft economic analysis of the proposed designation.

DATES: We will accept comments on the proposed rule or draft economic analysis that are received or postmarked on or before September 13, 2021. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by August 27, 2021.

ADDRESSES: You may submit comments on the proposed rule or draft economic analysis by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. In the Search box, enter FWS–R4–ES–2020–0062, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on

the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment Now!"

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R4-ES-2020-0062, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Document availability: The draft economic analysis is available at <http://www.fws.gov/mississippiES/>, at <http://www.regulations.gov> under Docket No. FWS-R4-ES-2020-0062.

The coordinates or plot points or both from which the maps are generated are included in the administrative record for this critical habitat designation and are available at <http://www.fws.gov/mississippiES/>, at <http://www.regulations.gov> under Docket No. FWS-R4-ES-2020-0062. Any additional tools or supporting information that we may develop for this critical habitat designation will also be available at the Service website and Field Office set out above, and may also be included in the preamble and/or at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Stephen Ricks, Field Supervisor, U.S. Fish and Wildlife Service, Mississippi Ecological Services Field Office, 6578 Dogwood View Parkway, Jackson, MS 39213; telephone 601-321-1122. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. Designations of critical habitat can only be completed by issuing a rule.

What this document does. This document proposes to designate critical habitat for the pearl darter in the Pascagoula River and Pearl River basins in Mississippi. We listed the pearl darter as a threatened species under the Act on September 20, 2017 (82 FR 43885).

The basis for our action. Section 4(a)(3) of the Act requires the Secretary

of the Interior (Secretary) to designate critical habitat to the maximum extent prudent and determinable for species listed as endangered or threatened species. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best available scientific data after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Economic impacts. In accordance with section 4(b)(2) of the Act, we prepared an analysis of the economic impacts of the proposed critical habitat designation. In this document, we announce the availability of the draft economic analysis for public review and comment.

Peer review. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we will seek peer review of this proposed rule. We are seeking comments from independent specialists to ensure that our critical habitat proposal is based on scientifically sound data and analyses. We have invited these peer reviewers to comment on our specific assumptions and conclusions in this critical habitat proposal during the public comment period for this proposed rule (see **DATES**, above).

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, Native American tribes, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as "critical

habitat" under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may not be prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(2) Specific information on:

(a) The amount and distribution of the pearl darter's habitat;

(b) What areas that were occupied at the time of listing and that contain the physical or biological features essential to the conservation of the species should be included in the designation and why;

(c) Any additional areas occurring within the range of the species, *i.e.*, rivers and streams within the Pearl River and Pascagoula River drainages in Mississippi and Louisiana, that should be included in the designation because they (1) are occupied at the time of listing and contain the physical or biological features that are essential to the conservation of the species and that may require special management considerations, or (2) are unoccupied at the time of listing and are essential for the conservation of the species;

(d) Special management considerations or protection that may be needed in occupied critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(e) What areas not occupied at the time of listing are essential for the conservation of the species. We particularly seek comments:

(i) Regarding whether occupied areas are inadequate for the conservation of the species;

(ii) Providing specific information regarding whether or not unoccupied areas would, with reasonable certainty, contribute to the conservation of the species and contain at least one physical

or biological feature essential to the conservation of the species;

(iii) Explaining whether or not unoccupied areas fall within the definition of “habitat” at 50 CFR 424.02 and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the pearl darter and proposed critical habitat.

(5) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the benefits of including or excluding areas that may be impacted.

(6) Information on the extent to which the description of probable economic impacts in the draft economic analysis is a reasonable estimate of those impacts.

(7) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act. For any additional areas that you may request be excluded from the designation, we will undertake an exclusion analysis if you provide credible information regarding the existence of a meaningful economic or other relevant impact supporting a benefit of inclusion or if we otherwise decide to exercise the discretion to evaluate the areas for possible exclusion.

(8) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via <http://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you

may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <http://www.regulations.gov>.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on <http://www.regulations.gov>.

Because we will consider all comments and information we receive during the comment period, our final critical habitat designation may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that some additional areas meet the definition of critical habitat, and some areas proposed as critical habitat may not meet the definition of critical habitat. In addition, we may find that the benefit of excluding some areas outweigh the benefits of including those areas pursuant to section 4(b)(2) of the Act, and we may exclude them from the final designation unless we determine that exclusion would result in extinction of the pearl darter.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service’s website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

Please refer to the final listing rule for the pearl darter, which published in the **Federal Register** on September 20, 2017 (82 FR 43885), for a detailed description of previous Federal actions concerning this species.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in

accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species’ occurrences, as determined by the Secretary (*i.e.*, range). Such areas may include those areas used throughout all or part of the species’ life cycle, even if not used on a regular basis (*e.g.*, migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals). Additionally, our regulations at 50 CFR 424.02 define the word “habitat” as follows: “For the purposes of designating critical habitat only, habitat is the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.”

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Designation also does not allow the government or public to access private lands. Designation does not require implementation of

restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement “reasonable and prudent alternatives” to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act’s definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act’s definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the

species would be inadequate to ensure the conservation of the species. In addition, for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts’ opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2)

regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species’ habitat or range is not a threat to the species, or threats to the species’ habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

No imminent threat of take attributed to collection or vandalism under Factor B was identified in the final listing rule for the pearl darter, and identification and mapping of critical habitat is not

expected to initiate any such threat. In our final listing determination for the pearl darter, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to this species and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances set forth in our regulations at 50 CFR 424.12(a)(1) has been met and because there are no other circumstances the Secretary has identified for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the pearl darter.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the pearl darter is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

- (i) Data sufficient to perform required analyses are lacking, or
- (ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of “critical habitat.”

When we published the proposed listing rule (81 FR 64857; September 21, 2016) and then the final listing rule (82 FR 43885; September 20, 2017) for the pearl darter, a careful assessment of the economic impacts of an associated critical habitat designation was incomplete, leading us to find that critical habitat was not determinable. We continued to review the available information related to the draft economic analysis, as well as newly acquired biological information necessary to perform this assessment. This and other information represent the best scientific data available, and we now find the data are sufficient for us to analyze the impacts of critical habitat designation. Accordingly, we conclude that the designation of critical habitat is determinable for the pearl darter.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat within the geographical area occupied by the species at the time of listing, we

consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define “physical or biological features essential to the conservation of the species” as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, the Service may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

Habitats Representative of the Historical, Geographical, and Ecological Distributions of the Species

The pearl darter is historically known from rivers and streams within the Pearl River and Pascagoula River drainages in

Mississippi and Louisiana, and the species was described from the lower Strong River within the Pearl River drainage of Mississippi (Suttkus *et al.* 1994, pp. 15–20). The darter has been extirpated from the Pearl River drainage for several decades, apparently due to system-wide channel and water quality degradation occurring in the late 1960s to early 1970s (Wagner *et al.* 2017, entire). With this extirpation, at least half of the historical, geographical, and ecological habitats of the pearl darter are no longer occupied. Channel integrity and water quality within the Pearl River drainage has since improved due to the enactment of State and Federal laws and regulations addressing water pollution and in-channel sand and gravel mining. In the lower Strong River, channel integrity is controlled and protected by natural bedrock outcrops, and water quality has improved, as indicated by the resurgence of other benthic fish species that historically co-occurred with the pearl darter (Piller *et al.* 2004, pp. 1007–1011; Tipton *et al.* 2004, pp. 57–60; Wagner *et al.* 2018, entire).

Within the Pascagoula River drainage, the pearl darter occurs within the Pascagoula, Chickasawhay, Leaf, Chunky, and Bouie Rivers and the Okatoma and Black Creeks (Wagner *et al.* 2017, pp. 3–10, 12; Clark *et al.* 2018, pp. 100–103; Schaefer *et al.* 2020, pp. 26–27, 43–44).

The lower Strong River within the Pearl River drainage and the rivers and streams identified above within the Pascagoula River drainage are representative of the historical, geographical, and ecological distribution of the species.

Space for Individual and Population Growth and for Normal Behavior

The pearl darter is found in free-flowing, low-gradient streams and rivers with pools and scour holes associated with channel bends and runs (Slack *et al.* 2002, p. 10; Bart *et al.* 2001, p. 13). Presence of the darter is associated with coarse sand and gravel substrates and woody debris, which also supplies habitats for its prey. Other bottom substrates associated with the species include sand, silt, loose clay, and gravel, with organic matter in the form of coarse and fine particulates and snag material (Slack *et al.* 2005, pp. 9, 11). Pearl darter occurrence within these habitats may be seasonal, with spawning occurring in upstream reaches, and growth and recruitment in downstream reaches (Bart *et al.* 2001, pp. 13, 15). Therefore, a continuum of perennial, uninterrupted, and interconnected natural small stream-to-river channel habitat is required for the

downstream drift of larvae or movement of juveniles, and the upstream migration of spawning adults.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

The pearl darter requires unimpeded and interconnected stretches of perennial and flowing streams and rivers with adequate water quality. Water temperatures at pearl darter collection sites has ranged from 8 to 30 degrees Celsius (°C) (46.4 to 86.0 degrees Fahrenheit (°F)) (Suttkus *et al.* 1994, pp. 17–19; Bart *et al.* 2001, p. 13; Slack *et al.* 2002, p. 10), with dissolved oxygen of 5.8 to 9.3 milligrams per liter (mg/l) (Suttkus *et al.* 1994, pp. 17–19; Bart *et al.* 2001, pp. 7, 13–14; Slack *et al.* 2002, p. 10). The species is apparently sensitive to warmer water temperatures and may seasonally require tributaries with canopy shading and/or cool spring flows as seasonal refugia from warmer, unshaded river channels (Bart *et al.* 2001, p. 14).

The natural diet of the pearl darter is poorly known; however, other species within the genus feed on chironomids (midges), small crustaceans, mayflies, and caddisflies (Kuehne and Barbour 1983, p. 49). Food availability is likely affected by adequate flow, channel stability, and water quality. Pearl darters have been maintained in captivity for at least 2 years on a diet of bloodworms (Campbell 2019, p. 1).

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Pearl darters have been collected at sites with cool to warm water temperatures (8 to 30 °C (46.4 to 86.0 °F)), high dissolved oxygen (5.8 to 9.3 mg/l), slightly acidic to basic pH values (6.3 to 7.6), and apparently low levels of pollution (Suttkus *et al.* 1994, pp. 17–19; Bart *et al.* 2001, pp. 7, 13–14; Slack *et al.* 2002, p. 10). Spawning in the Strong River was associated with bedrock and broken rubble (Suttkus *et al.* 1994, p. 19), and three probable spawning sites in the Pascagoula River system were characterized by extensive outcrops of limestone or sandstone (Bart and Pillar 1997, p. 8). Pearl darters in spawning condition in the Pascagoula River drainage have also been collected over firm gravel in relatively shallow, flowing water from April to early May (Bart *et al.* 2001, p. 13). Ideal conditions for spawning have been described as channel reaches with good canopy shading, an extensive buffer of mature forest, and good water quality (Bart *et al.* 2001, p. 15).

Spawning in the Pearl and Strong Rivers (Mississippi) was documented

during March through May (Suttkus *et al.* 1994, pp. 19–20), and young of year were collected in June (Suttkus *et al.* 1994, p. 19). Based on collection occurrence patterns, some researchers have postulated that adult pearl darters migrate upstream during the fall and winter to spawn in suitable upstream gravel reaches, with elevated river discharge during the spring dispersing the larvae and juveniles into downstream reaches (Bart *et al.* 2001, p. 14; Ross *et al.* 2000, p. 11). Other studies have hypothesized that the species disperses locally from shallow spawning habitats into nearby deeper habitats where their presence is more difficult to detect (Slack *et al.* 2002, p. 18). The pattern of the disappearance of the pearl darter from all stream orders in the Pearl River drainage over a relatively short period of time suggests that some degree of seasonal interchange between tributary and river channel subpopulations may have been a factor in the species' extirpation from that drainage. Therefore, until more is known relative to seasonal dispersal, connectivity between instream habitats should be considered essential for successful breeding and rearing of the pearl darter.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the pearl darter from studies of this species' habitat, ecology, and life history. Additional information can be found in the September 21, 2016, proposed listing rule (81 FR 64857) and the September 20, 2017, final listing rule (82 FR 43885). We have determined that the following physical or biological features are essential to the conservation of the pearl darter:

(1) Unobstructed and stable stream and river channels with:

(a) Connected sequences of channel runs and bends associated with pools and scour holes; and

(b) Bottom substrates consisting of fine and coarse sand, gravel, bedrock, silt, clay, organic matter, or woody debris.

(2) A natural flow regime necessary to maintain instream habitats and their connectivity.

(3) Water quality conditions, including cool to warm water temperatures (8 to 30 °C (46.4 to 86.0 °F)), high dissolved oxygen (5.8 to 9.3 mg/l), slightly acidic to basic pH (6.3 to 7.6), and low levels of pollutants and nutrients meeting the current State of Mississippi criteria, as necessary to maintain natural physiological processes for normal behavior, growth,

and viability of all life stages of the species.

(4) Presence of a prey base of small aquatic macroinvertebrates, including midges, crustaceans, mayflies, caddisflies, and zooplankton.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features that are essential to the conservation of the species and which may require special management considerations or protection. The pearl darter is threatened by water quality degradation from point and nonpoint source pollution, discharges from municipalities, and geomorphological changes to its channel habitats (82 FR 43885, September 20, 2017, pp. 43888–43893). The features essential to the conservation of this species may require special management considerations or protection to reduce the following threats: (1) Actions that alter the minimum or existing flow regime, including impoundment, channelization, or water diversion; (2) actions that significantly alter water chemistry or temperature by the release of chemicals, biological pollutants, or heated effluents into the surface water or connected groundwater at a point or non-point source; and (3) actions that significantly alter channel morphology or geometry, including channelization, impoundment, road and bridge construction, or instream mining.

Examples of special management actions that would minimize or ameliorate these threats include: (a) Restoration and protection of riparian corridors; (b) implementation of best management practices to minimize erosion (such as State and industry practices for road construction, forest management, or mining activities); (c) stream bank restoration projects; (d) private landowner programs to promote watershed and soil conservation (such as the U.S. Department of Agriculture's Farm Bill and the Service's Private Lands programs); (e) implementation of best management practices for storm water; and (f) upgrades to industrial and municipal treatment facilities to improve water quality in effluents.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available

information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species at the time of listing to be considered for designation as critical habitat.

The current distribution of the pearl darter is reduced from its historical distribution, and we anticipate that recovery will require continued protection of the existing population and habitat, as well as establishing a population within its historical range, to ensure there are adequate numbers of pearl darters occurring in stable populations for the species' continued conservation. Furthermore, rangewide recovery considerations, such as maintaining existing genetic diversity and striving for representation of all major portions of the species' historical range, were considered in formulating this proposed critical habitat designation.

We are proposing to designate critical habitat in areas within the geographical area occupied by the species at the time of listing. We identified areas with current occurrence records that we deemed suitable habitat (see delineation steps, below) and that had one or more of the physical or biological features identified for the pearl darter which may require special management considerations or protection. We also are proposing to designate specific areas outside of the geographical area occupied by the species at the time of listing because we have determined that a designation limited to occupied areas would be inadequate to ensure the conservation of the species. For those unoccupied areas, we have determined that it is reasonably certain that the unoccupied areas will contribute to the conservation of the species and contain one or more of the physical or biological features that are essential to the conservation of the species. We have also determined that the unoccupied areas fall within the regulatory definition of "habitat" at 50 CFR 424.02.

Threats to pearl darters occurring in the Pascagoula River drainage are compounded by the species' naturally low numbers and short life span, but the species' conservation potential is primarily limited by its extirpation from the Pearl River drainage and, therefore, its lack of redundancy. The documented Pearl River drainage extirpation was rapid and system-wide, including all mainstem and tributary collection sites seemingly simultaneously. As such, we consider pearl darters occurring within the Pascagoula River and its tributaries

as a single population. The loss of the species' redundancy, with its extirpation from the Pearl River drainage, has also diminished its genetic and ecological representation, and, therefore, increased the species' vulnerability to catastrophic events and population changes. A successful reintroduction into the Pearl River drainage would restore the species' redundancy within the historical range. In addition, the pearl darter's representation would increase from current levels by allowing for local environmental adaptation and increasing genetic representation. Thus, reintroducing the species into the Pearl River drainage would contribute to the resilience and conservation of the pearl darter.

Factors implicated in the Pearl River extirpation include geomorphic instability (*i.e.*, channel erosion and degradation), sedimentation, and point source pollution from municipalities and industries (*e.g.*, Bart and Suttkus 1995, p. 14; Tipton *et al.* 2004, pp. 59–60). One or all of these factors may have been responsible for the diminishment or loss of some or all of the physical or biological features essential to the conservation of the pearl darter within the drainage (*e.g.*, channel stability, substrate, water quality, prey base). We now find that these factors have been reduced to a degree that the pearl darter may be successfully reintroduced into the Pearl River.

For example, active channel erosion and degradation that may have been precipitated by the 1956 construction of the Pearl River navigation system in the lower basin, and aggravated by the 1963 construction of the Ross Barnett Reservoir in the upper basin, have diminished, and instream mining is now prohibited by the States of Mississippi and Louisiana, resulting in more stable channel habitats within the basin. In addition, point-source pollution from untreated municipal and industrial discharge into the Pearl River has been significantly reduced by enactment and enforcement of the Clean Water Act of 1972 (33 U.S.C. 1251 *et seq.*). The improvement of the physical or biological features within the Pearl River drainage is also demonstrated by recent observed increases in other benthic fish species (*e.g.*, crystal darter (*Crystallaria asprella*) and frecklebelly madtom (*Noturus munitus*)), which experienced declines concurrent with the extirpation of the pearl darter (Piller *et al.* 2004, pp. 1007–1011; Tipton *et al.* 2004, pp. 57–60; Wagner *et al.* 2018, p. 13). These improvements leave us reasonably certain that all of the physical or biological features essential

to the conservation of the pearl darter are now present within the Pearl River drainage. Because the Pearl River drainage habitat contains the physical or biological features for the pearl darter and supports other benthic fish species with similar life processes, we conclude that the drainage contains the resources and conditions necessary to support the life processes for the pearl darter.

For this proposed rule, we completed the following steps to delineate critical habitat:

(1) We compiled all available current and historical occurrence data records for the pearl darter in both the Pascagoula and Pearl River drainages;

(2) We used confirmed presence from 1994–2019 as the foundation for identifying areas currently occupied in the Pascagoula River drainage;

(3) We evaluated habitat suitability of stream segments that contain the identified physical or biological features and that are currently occupied by the species, and we retained all occupied stream segments;

(4) We evaluated unoccupied segments of the Pearl River drainage for suitability of spawning and recruitment, darter reintroduction, and monitoring and management of a reintroduced population; and

(5) We evaluated unoccupied segments of the Pearl River drainage for connectivity with reaches historically occupied and identified areas containing the physical or biological features essential to the conservation of the species that may require special management considerations or protection.

Sources of data for this proposed critical habitat designation include the proposed and final listing rules (81 FR 64857, September 21, 2016; 82 FR 43885, September 20, 2017), fish collection databases provided by the MDWFP, survey reports and observations, and peer-reviewed publications.

Areas Occupied at the Time of Listing

We used reports and collection data to map species site collections and occurrences between 1994 and 2019 to determine areas occupied at the time of listing. Based on the best available scientific data, we determined that all currently known occupied habitat for the pearl darter was also occupied by the species at the time of listing, and that these areas contain the physical or biological features essential to the conservation of the species and which may require special management considerations or protection.

As stated above, we delineated units based on documented occurrences and

the existing physical or biological features essential to the conservation of the species. Collection occurrence patterns suggest that adult pearl darters migrate upstream to spawn in suitable gravel or bedrock reaches, with elevated spring river discharge dispersing larvae and juveniles into downstream reaches; an alternative hypothesis considers that the pearl darter moves from shallow, easily collected spawning habitats into deeper habitats where it is more difficult to detect the fish (see *Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring*, above). While both hypotheses are partially supported by data, we note that the disappearance of the species from the Pearl River drainage occurred fairly rapidly and simultaneously in all stream orders, suggesting some element of migration may be involved in the darter's life history. To allow for potential seasonal movement between stream reaches, we propose to designate one continuous unit of occupied critical habitat within the Pascagoula River drainage. This unit includes portions of the Chunky, Bouie, Leaf, Chickasawhay, and Pascagoula Rivers, as well as reaches of Okatoma and Big Black Creeks, as described below under Proposed Critical Habitat Designation.

Since the 2017 listing of the species, there have been 71 site collections of pearl darter in the Pascagoula River drainage (Wagner *et al.* 2019, pp. 8–18; Schaefer *et al.* 2020, pp. 26–27, 43–44). One of these collections in 2018 extended the known range approximately 60 mi (97 km) in Black Creek, above its confluence with the occupied reach of Big Black Creek (Schaefer *et al.* 2020, pp. 26–27). We consider this additional mileage of stream reach to be occupied at the time of listing. This is because the reach between the previously identified population in Big Black Creek and the newly discovered population upstream has the physical or biological features essential to the conservation of the species, and the species potentially seasonally migrates. The potential for seasonal migration, the species' small size and rarity, and the fact that surveys for the pearl darter are difficult and not always definitive of the species' absence within a particular reach of an occupied stream also support considering this area occupied at the time of listing.

In making these determinations, we recognize that collection sites for the pearl darter occur at areas generally accessible to fish biologists and that occupied habitats within a river reach may vary depending upon life stage, stream size, and season. Additionally, stream habitats are highly dependent

upon upstream and downstream channel habitat conditions for their maintenance. Therefore, we considered the areas occupied at the time of listing to extend from an identifiable landmark (e.g., bridge crossing, tributary confluence, etc.) nearest the uppermost records within second or third order streams, through their confluence with third and fourth order streams, downstream to an identifiable landmark near the lowermost areas of collection in the Pascagoula River (*i.e.*, forks of the East and West Pascagoula River). Within the current range of the pearl darter within the Pascagoula River drainage, some habitats may or may not be actively used at all times by individuals; however, these areas are necessary for maintaining population connectivity, as well as other physical or biological features essential to the conservation of the species, and, therefore, are considered the geographic area occupied at the time of listing for the pearl darter. This area (referred to below as proposed Unit 1) contains all of the physical or biological features essential to the conservation of the pearl darter and which may require special management conditions or protections.

Areas Unoccupied at the Time of Listing

To consider for designation areas not occupied by the species at the time of listing, we must demonstrate that these areas are essential for the conservation of the pearl darter. The proposed occupied critical habitat does not include geographic areas within the Pearl River drainage—the only other area in which the pearl darter historically occurred—as it has been extirpated from that drainage. In addition, because the Pascagoula River drainage population is the only extant population, that population provides no redundancy for the species. Based upon the species' rapid and system-wide extirpation from the Pearl River drainage, a series of back-to-back stochastic events or a single catastrophic event could similarly significantly reduce resiliency or extirpate the Pascagoula River population. For these reasons, we determined we cannot conserve the species by designating only occupied habitat as it includes only a single population in a single drainage. Thus, we determined that habitat in another historical drainage is needed for the long-term survival and recovery of the species. Therefore, because we determined that the one occupied area alone is not adequate for the conservation of the species, we have identified and are proposing for designation as critical habitat specific areas outside the geographical area

occupied by the species at the time of listing that are essential for the conservation of the species. We used historical occurrence data and the physical or biological features described earlier to identify unoccupied habitat essential for the conservation of the pearl darter.

Based on our review, we determined that the lower Strong River, a major tributary of the Pearl River, has the potential for future reintroduction and reoccupation by the pearl darter, provided that stressors are managed and mitigated. Reestablishing a viable population in the Strong River will restore the species' redundancy within the historical range and increase the species' ecological representation. The specific area encompasses the minimum area of the species' historical range within the Pearl River drainage, while still providing ecological diversity so that the species can evolve and adapt over time. This river reach also provides the potential for the pearl darter to expand its range into other historically occupied areas, which currently may be or may later become suitable, to ensure that the species has an adequate level of redundancy within the Pearl River drainage and guard against future catastrophic events. The lower Strong River also represents the stream reach within the historical range with the best potential for recovery of the species due to current conditions, suitability for reintroductions, and access for monitoring.

Accordingly, we propose to designate one unoccupied unit in the lower Strong River within the Pearl River drainage. As described below in the individual unit descriptions, this unit contains all of the physical or biological features essential to the conservation of the species and is reasonably certain to contribute to the conservation of the species.

General Information on the Maps of the Proposed Critical Habitat Designation

The areas proposed as critical habitat include only stream channels within the ordinary high-water line. There are no developed areas within the critical habitat boundaries except for transportation and pipeline crossings, which do not remove the suitability of these areas for the pearl darter. When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the pearl darter. The scale of the maps we prepared under the parameters for publication within the

Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

The proposed critical habitat designation is defined by the map or

maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in our discussion of the individual units below. We will make the coordinates or plot points or both on which each map is based available to the public on <http://www.regulations.gov> under Docket No. FWS-R4-ES-2020-0062 and on our internet site <http://www.fws.gov/mississippiES/>.

Proposed Critical Habitat Designation

We are proposing to designate approximately 517 mi (832 km) of river

and stream channels in two units as critical habitat for the pearl darter. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the pearl darter. The two areas we propose as critical habitat are: (1) Pascagoula River Unit; and (2) Strong River Unit. Ownership of stream channel bottoms included in this proposed rule are determined by riparian land ownership. The table below shows the occupancy of the units, the riparian land ownership, and approximate lengths of the proposed critical habitat for the pearl darter.

TABLE OF PROPOSED CRITICAL HABITAT UNITS FOR PEARL DARTER
[Unit length estimates include only stream channels within the ordinary high-water line]

Unit	Occupancy	Riparian land ownership				Total mi (km)
		Federal mi (km)	State mi (km)	County mi (km)	Private mi (km)	
1. Pascagoula River	Occupied	** 45 (72)	** 76 (122)		373 (600)	** 487 (783)
2. Strong River	Unoccupied			0.4 (0.6)	30 (48.4)	30 (49)
Total km (mi)		** 45 (72)	** 76 (122)	0.4 (0.6)	403 (648.4)	** 517 (832)

** 7 mi (11 km) of pearl darter critical habitat stream miles shared between State and Federal lands.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for pearl darter, below.

Unit 1: Pascagoula River Unit

Unit 1 consists of 487 mi (783 km) of occupied connected river and stream channels within the Pascagoula River drainage in Mississippi, including:

- 63 mi (102 km) of the Pascagoula River channel from its confluence with the West Pascagoula River in Jackson County, upstream to the confluence of the Leaf and Chickasawhay Rivers in George County;
- 80 mi (129 km) of Big Black Creek/Black Creek channel from its confluence with the Pascagoula River in Jackson County, upstream to U.S. Highway 49 Bridge in Forrest County;
- 160 mi (257 km) of Chickasawhay River channel from its confluence with the Leaf River just north of Enterprise, Clarke County, upstream to the confluence of Okatibbee Creek and Chunky River in Clarke County;
- 21 mi (34 km) of Chunky River channel from its confluence with Okatibbee Creek in Clarke County, upstream to second Highway 80 Crossing in Newton County;
- 119 mi (192 km) of Leaf River channel from its confluence with the Chickasawhay River in George County,

upstream to the bridge crossing at U.S. Highway 84 in Covington County;

- 15 mi (24 km) of Bouie River channel from its confluence with the Leaf River, upstream to the confluence of Okatoma Creek in Forrest County; and
- 28 mi (45 km) of Okatoma Creek from its confluence with the Bouie River in Forrest County, upstream to the bridge crossing at U.S. Highway 84 in Covington County.

The riparian lands (channel borders) in this unit are generally privately owned agricultural or silvicultural lands, with short reaches owned and managed by the U.S. Forest Service or the State (see table above). All channel segments in Unit 1 are occupied by the pearl darter, and the unit contains all the physical or biological features essential to the conservation of the species, including deep pools, runs, and bends and scour holes; mixtures of bottom substrates of sand, silt, loose clay and gravel, fine and coarse particles of organic matter, and snag material; a natural hydrograph with flows and water quality that currently support the normal life stages of the pearl darter; and the species' prey sources.

Special management considerations and protections that may be required to address threats within the unit include minimizing surface water withdrawals

or other actions that alter stream flow; reducing excessive use of manures, fertilizers, and pesticides near stream channels; improving treatment of wastewater discharged from permitted facilities; and implementing practices that protect or restore riparian buffer areas along stream corridors.

Unit 2: Strong River Unit

Unit 2 consists of 30 mi (49 km) of unoccupied habitat in the Strong River channel from its confluence with the Pearl River, upstream to U.S. Highway 49, in Simpson County, Mississippi. The riparian lands in this unit are generally privately owned agricultural or silvicultural lands, with a short channel reach (0.39 mi (0.63 km)) owned and operated by the Simpson County Park Commission (see table above). Unit 2 is not within the geographic range occupied by the pearl darter at the time of listing, but this area was historically known to provide spawning and recruitment habitat prior to the species' extirpation from the Pearl River drainage. This unit currently provides all physical or biological features essential to the conservation of the pearl darter, including a stable channel with bottom substrates of sand, silt, loose clay and gravel, bedrock, fine and coarse particles of organic matter, and woody debris; a natural hydrograph

with flows and water quality to support the normal life stages of the pearl darter and the species' prey sources. Further evidence of the presence of physical or biological features within this reach of the Strong River is demonstrated by recent increases in other benthic fish species (e.g., frecklebelly madtom) that declined concurrent with the extirpation of the pearl darter (Piller *et al.* 2004, pp. 1007–1011; Wagner *et al.* 2018, pp. 4–5).

As described above, the best available information demonstrates that the pearl darter disappeared from the entire Pearl River and all known tributary segments virtually simultaneously. Therefore, it is possible that a series of back-to-back stochastic events or a single catastrophic event could significantly reduce or extirpate the surviving pearl darter population within the Pascagoula River drainage. Due to the species' lack of redundancy, its naturally small numbers within the Pascagoula River drainage, and its short life span, the pearl darter is more vulnerable to existing and future threats, including habitat degradation and loss, catastrophic weather events, and introduced species. This unit would serve to protect habitat needed to reestablish a wild population within the historical range in the Pearl River drainage and recover the species. Re-establishing a population of the pearl darter within Unit 2 would also increase the species' redundancy and restore ecological representation, better ensuring its survival if a stochastic event were to impact the Pascagoula River population. This unit is essential for the conservation of the species because it will provide habitat for range expansion in known historical habitat that is necessary to increase viability of the pearl darter by increasing its resiliency, redundancy, and representation.

The need for reintroduction of the pearl darter into the Pearl River drainage has been recognized and is being discussed by our conservation partners. The landowner of the type locality (location where the species was described) within the Strong River unit has been working with the Service and MDWFP to regularly monitor for the presence of the pearl darter and other benthic fish, and expressed interest in reestablishing the species on the property. Methods and facilities for propagating the species have been developed, tested, and proven at a Service fish hatchery. Accordingly, we are reasonably certain this unit will contribute to the conservation of the pearl darter.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2), is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we

provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define “reasonable and prudent alternatives” (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation, we have listed a new species or designated critical habitat that may be affected by the Federal action, or the action has been modified in a manner that affects the species or critical habitat in a way not considered in the previous consultation. In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the “Destruction or Adverse Modification” Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As

discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Services may, during a consultation under section 7(a)(2) of the Act, find are likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would block or disconnect stream and river channels. Such activities could include, but are not limited to, the construction of dams or weirs, channelization, and mining. These activities could result in destruction of habitat, block movements between seasonal habitats, fragment and isolate subpopulations within critical habitat units, and/or affect flows within or into critical habitat.

(2) Actions that would affect channel substrates and stability. Such activities include channelization, impoundment, mining, road and bridge construction, removal of riparian vegetation, and land clearing. These activities may lead to changes in channel substrates, erosion of the streambed and banks, and excessive sedimentation that could degrade pearl darter habitat.

(3) Actions that would reduce flow levels or alter flow regimes. These could include, but are not limited to, activities that block or lower surface flow or groundwater levels, including channelization, impoundment, groundwater pumping, and surface water withdrawal or diversion. Such activities can result in long-term changes in stream flows that affect habitat quality and quantity for the darter and its prey.

(4) Actions that would affect water chemistry or temperature or introduce pollutants and nutrients at levels above State of Mississippi criteria. Such activities include, but are not limited to, the release of chemical pollutants, biological pollutants, or heated effluents into the surface water or connected groundwater at a point source or by dispersed release (nonpoint source). These activities could alter water quality conditions to levels that are beyond the tolerances of the pearl darter or its prey species.

(5) Actions that would result in the introduction, spread, or augmentation of

nonnative aquatic species in occupied stream segments, or in stream segments that are hydrologically connected to occupied stream segments, even if those segments are occasionally intermittent, or the introduction of other species that compete with or prey on the pearl darter. Possible actions could include, but are not limited to, stocking of nonnative fishes or other related actions. These activities can also introduce parasites or disease, or affect the growth, reproduction, and survival of the pearl darter.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographic areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. There are no DoD lands with a completed INRMP within the proposed critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if they determine that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless they determine, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both “with critical habitat” and “without critical habitat.”

The “without critical habitat” scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (e.g., under the Federal listing as well as other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.*, conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The “with critical habitat” scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the

pearl darter (IEc 2020, entire). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out particular geographic areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.*, absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. If there are any unoccupied units in the proposed critical habitat designation, the screening analysis assesses whether any additional management or conservation efforts may incur incremental economic impacts. This screening analysis combined with the information contained in our IEM are what we consider our draft economic analysis (DEA) of the proposed critical habitat designation for the pearl darter; our DEA is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for the pearl darter, first we identified, in the IEM dated April 21, 2020, probable incremental economic impacts associated with the following categories of activities: (1) Roadway and bridge construction and repair; (2) commercial

or residential development; (3) dredging; (4) groundwater pumping; (5) instream dams and diversions; (6) storage, distribution, or discharge of chemical pollutants; (7) oil and gas; (8) utilities; (9) water quantity and supply; and (10) water quality. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In areas where the pearl darter is present, Federal agencies already are required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.*, difference between the jeopardy and adverse modification standards) for the pearl darter's critical habitat. The following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to the pearl darter would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The proposed critical habitat designation for the pearl darter totals approximately 517 mi (832 km) of river and stream channels in two units. Riparian lands bordering the proposed critical habitat are under private (78 percent), county (0.1 percent), State (15 percent), and Federal (9 percent) ownership. A small portion (1.3 percent) has shared State and Federal ownership. Unit 1 is occupied by the pearl darter and represents 94 percent of

the proposed critical habitat. Within this occupied unit, any actions that may affect the species or its habitat would also affect designated critical habitat, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the pearl darter. Therefore, only administrative costs are expected in actions affecting this unit. While this additional analysis will require time and resources by both the Federal action agency and the Service, it is believed that, in most circumstances, these costs, because they are predominantly administrative in nature, would not be significant.

Unit 2 is currently unoccupied by the species but is essential for the conservation of the species. This unit totals 30 mi (49 km) and comprises 6 percent of the total proposed critical habitat designation. In this unoccupied area, any conservation efforts or associated probable impacts would be considered incremental effects attributed to the critical habitat designation. However, two threatened species, Gulf sturgeon (listed as Atlantic sturgeon (Gulf subspecies), *Acipenser oxyrinchus desotoi*) and ringed map turtle (*Graptemys oculifera*), currently occupy this unit, and conservation efforts to protect these species would also protect pearl darter critical habitat.

The DEA finds that the total annual incremental costs of critical habitat designation for the pearl darter are not anticipated to reach \$100 million in any given year based on the anticipated annual number of consultations and associated administrative costs, which are not expected to exceed \$710,000 in any year.

In Unit 1, which constitutes 94 percent of the proposed critical habitat area, the activities that may affect the critical habitat are already subject to section 7 consultation due to the presence of pearl darter. We determined that the project modification recommendations made to avoid jeopardy to the pearl darter would also result in the avoidance of adverse modification. Thus, for projects and activities occurring in Unit 1, no additional project modification recommendations are likely to result from the proposed critical habitat rule and costs are limited to additional administrative effort.

A relatively small fraction (6 percent) of the proposed critical habitat designation is in Unit 2, which is not currently occupied by the species. In these areas, activities that may affect the

critical habitat for the pearl darter are also already subject to section 7 consultation due to the presence of other listed species with similar habitat requirements and designated critical habitat. Additionally, activities that may affect pearl darter critical habitat in Unit 2 generally implement project modification recommendations from a standardized set provided in the Mississippi Standard Local Operations Procedures for Endangered Species (SLOPES) agreement. Through this agreement, enacted in June 2017, the U.S. Army Corps of Engineers (COE) and the Service have established routine procedures for jointly implementing section 7 requirements for all projects that require COE permits. The agreement requires the COE to consult species-specific SLOPES documents to determine if a project is expected to adversely affect the species or its habitat. As part of the agreement, species-specific avoidance and minimization measures have been established for COE projects. The measures described for the pearl darter are similar to the measures described for overlapping species and because the COE addresses permitting for projects with water impacts, all projects with a Federal nexus in the proposed pearl darter critical habitat are likely to follow the Mississippi SLOPES procedures and recommendations. Therefore, even absent critical habitat designation, these activities are likely to avoid adverse effects on the habitat.

We are soliciting data and comments from the public on the DEA discussed above, as well as all aspects of this proposed rule and our required determinations. During the development of a final designation, we will consider the information presented in the DEA and any additional information on economic impacts we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 17.90. If we receive credible information regarding the existence of a meaningful economic impact or other relevant impact supporting a benefit of exclusion, we will conduct an exclusion analysis for the relevant area or areas. We may also otherwise decide to exercise the discretion to evaluate any particular areas for possible exclusion. In addition, if we do conduct an exclusion analysis and we have received any information from experts in, or sources with firsthand knowledge about, impacts of the designation that are outside the

scope of the Service's expertise, for purposes of the exclusion analysis we will assign weights to those impacts consistent with the information from experts in, or sources with firsthand knowledge about, those impacts, unless we have rebutting information. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Consideration of National Security Impacts

Section 4(a)(3)(B)(i) of the Act may not cover all DoD lands or areas that pose potential national-security concerns (e.g., a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section 4(a)(3)(B)(i), national-security or homeland-security concerns are not a factor in the process of determining what areas meet the definition of "critical habitat." Nevertheless, when designating critical habitat under section 4(b)(2), the Service must consider impacts on national security, including homeland security, on lands or areas not covered by section 4(a)(3)(B)(i). Accordingly, we will always consider for exclusion from the designation areas for which DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns.

We cannot, however, automatically exclude requested areas. When DoD, DHS, or another Federal agency requests exclusion from critical habitat on the basis of national-security or homeland-security impacts, it must provide credible information, including a reasonably specific justification of an incremental impact on national security that would result from the designation of that specific area as critical habitat. That justification could include demonstration of probable impacts, such as impacts to ongoing border-security patrols and surveillance activities, or a delay in training or facility construction, as a result of compliance with section 7(a)(2) of the Act. If the agency requesting the exclusion does not provide us with a reasonably specific justification, we will contact the agency to recommend that it provide a specific justification or clarification of its concerns relative to the probable incremental impact that could result from the designation. If the agency provides a reasonably specific

justification, we will defer to the expert judgment of DoD, DHS, or another Federal agency as to: (1) Whether activities on its lands or waters, or its activities on other lands or waters, have national-security or homeland-security implications; (2) the importance of those implications; and (3) the degree to which the cited implications would be adversely affected in the absence of an exclusion. In that circumstance, in conducting a discretionary section 4(b)(2) exclusion analysis, we will give great weight to national-security and homeland-security concerns in analyzing the benefits of exclusion.

In preparing this proposal, we determined that the lands within the proposed designation of critical habitat for the pearl darter are not owned, managed, or used by the DoD or DHS, and, therefore, we anticipate no impact on national security or homeland security. However, during the development of a final designation we will consider any additional information received through the public comment period on the impacts of the proposed designation on national security or homeland security to determine whether to undertake the discretionary analysis to determine whether to exclude any specific areas from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 17.90.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. We consider a number of factors including whether there are permitted conservation plans covering the species in the area such as HCPs, safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs), or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at the existence of Tribal conservation plans and partnerships and consider the government-to-government relationship of the United States with Tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we determined that there are currently no HCPs or other management plans for pearl darter, and the proposed designation does not include any Tribal lands or trust resources. We anticipate no impact on Tribal lands, partnerships,

or HCPs from this proposed critical habitat designation. Additionally, as described above, we are not considering excluding any particular areas on the basis of impacts to national security or economic impacts.

During the development of a final designation, we will consider all information currently available or received during the public comment period. If we receive credible information regarding the existence of a meaningful impact supporting a benefit of excluding any area, we will undertake an exclusion analysis and determine whether those areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 17.90. We may also exercise the discretion to undertake exclusion analyses for other areas as well.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;
- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for

achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than \$5 million in annual sales, general and heavy construction businesses with less than \$27.5 million in annual business, special trade contractors doing less than \$11.5 million in annual business, and agricultural businesses with annual sales less than \$750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In

general, the term “significant economic impact” is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies would be directly regulated if we adopt the proposed critical habitat designation. There is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated by this rulemaking, the Service certifies that, if made final as proposed, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use— *Executive Order 13211*

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. In our economic analysis, we did not find that this proposed critical habitat designation would significantly affect energy supplies, distribution, or use.

Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act
(2 U.S.C. 1501 *et seq.*)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both “Federal intergovernmental mandates” and “Federal private sector mandates.” These terms are defined in 2 U.S.C. 658(5)–(7). “Federal intergovernmental mandate” includes a regulation that “would impose an enforceable duty upon State, local, or Tribal governments” with two exceptions. It excludes “a condition of Federal assistance.” It also excludes “a duty arising from participation in a voluntary Federal program,” unless the regulation “relates to a then-existing Federal program under which \$500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,” if the provision would “increase the stringency of conditions of assistance” or “place caps upon, or otherwise decrease, the Federal Government’s responsibility to provide funding,” and the State, local, or Tribal governments “lack authority” to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. “Federal private sector mandate” includes a regulation that “would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.”

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted

by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because it will not produce a Federal mandate of \$100 million or greater in any year, that is, it is not a “significant regulatory action” under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments and, as such, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the pearl darter in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the proposed designation of critical habitat for the pearl darter, and it concludes that, if adopted, this designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement

is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The proposed designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this proposed rule identifies the elements of physical or biological features essential to the conservation of the species. The proposed areas of

critical habitat are presented on maps, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) is not required. 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.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County v. Babbitt*, 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations

with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribal lands fall within the boundaries of the proposed critical habitat for the pearl darter, so no Tribal lands would be affected by the proposed designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at <http://www.regulations.gov> and upon request from the Mississippi Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Mississippi Ecological Services Field Office.

Signing Authority

The Director, U.S. Fish and Wildlife Service, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the U.S. Fish and Wildlife Service. Martha Williams, Principal Deputy Director Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service, approved this document on June 29, 2021, for publication.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by revising the entry for “Darter, pearl” under **FISHES** in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* * * * *				
FISHES				
* * * * *				
Darter, pearl	<i>Percina aurora</i>	Wherever found	T	82 FR 43885, 9/20/2017; 50 CFR 17.95(e). ^{CH}
* * * * *				

■ 3. Amend § 17.95(e) by adding an entry for “Pearl Darter (*Percina aurora*)” following the entry for “Niangua Darter (*Etheostoma nianguae*)” to read as set forth below:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes*.

* * * * *

Pearl Darter (*Percina aurora*)

(1) Critical habitat units are depicted for Clarke, Covington, Forrest, George, Greene, Jackson, Jones, Lauderdale, Newton, Perry, Simpson, Stone, and Wayne Counties, Mississippi, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of the pearl darter consist of the following components:

(i) Unobstructed and stable stream and river channels with:

(A) Connected sequences of channel runs and bends associated with pools and scour holes, and

(B) Bottom substrates consisting of fine and coarse sand, gravel, bedrock, silt, clay, organic matter, or woody debris.

(ii) A natural flow regime necessary to maintain instream habitats and their connectivity.

(iii) Water quality conditions, including cool to warm water temperatures (8 to 30 °C (46.4 to 86.0 °F)), high dissolved oxygen (5.8 to 9.3 mg/l), slightly acidic to basic pH (6.3 to 7.6), and low levels of pollutants and nutrients meeting the current State of Mississippi criteria, as necessary to maintain natural physiological processes for normal behavior, growth, and viability of all life stages of the species.

(iv) Presence of a prey base of small aquatic macroinvertebrates, including midges, crustaceans, mayflies, caddisflies, and zooplankton.

(3) Critical habitat includes only the stream channels within the ordinary

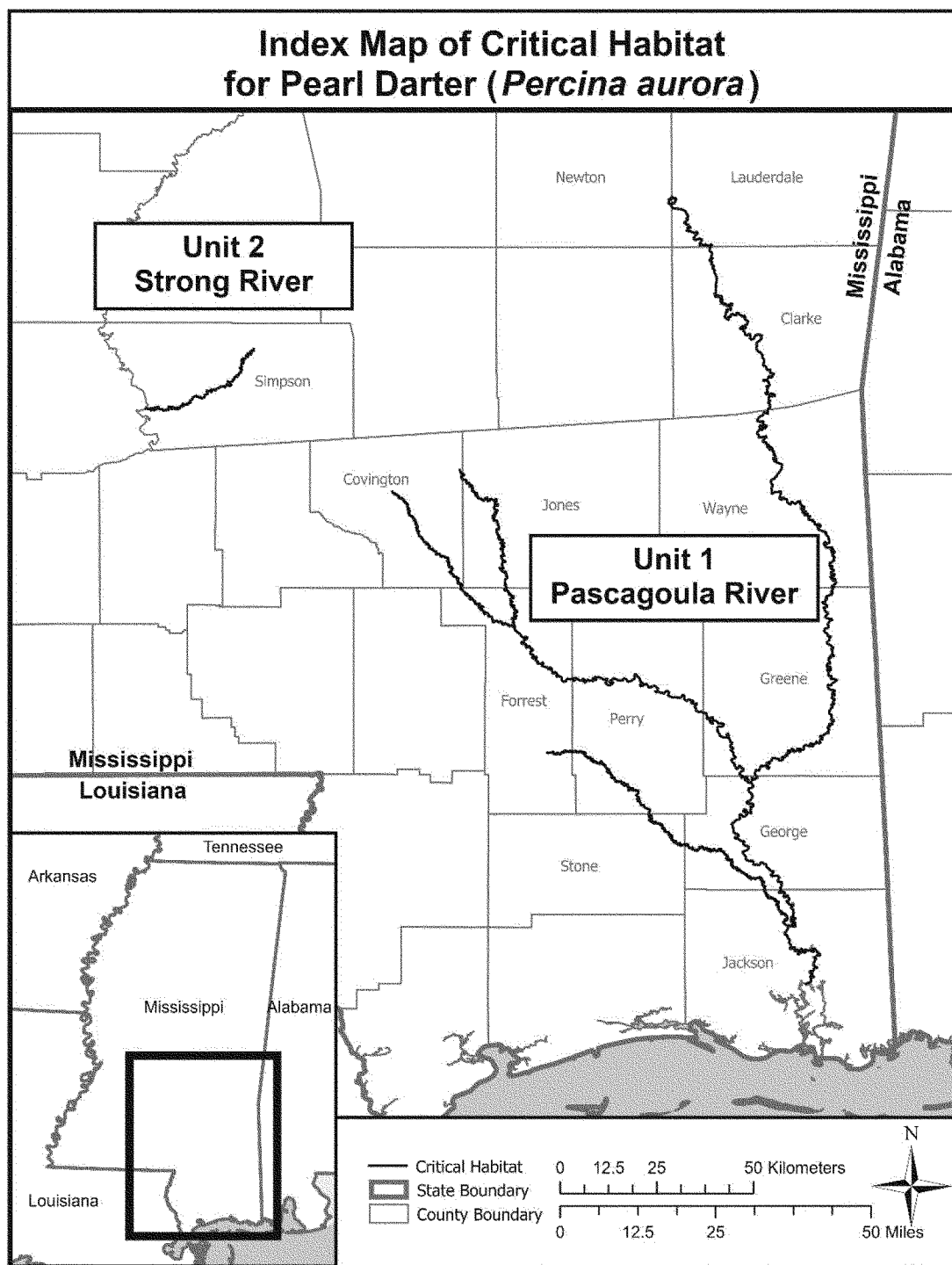
high water line, and does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the final rule.

(4) Data layers defining map units were created using U.S. Geological Survey's National Hydrography Dataset flowline data, on a base map of State and County boundaries from the U.S. Department of Agriculture's Natural Resources Conservation Service. Critical habitat units were mapped using the Geographic Coordinate System North American 1983 coordinates. The maps in this entry, as modified by any

accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site at <http://www.fws.gov/mississippiES/>, at <http://www.regulations.gov> under Docket No. FWS-R4-ES-2020-0062, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Note: Index map follows:

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(6) Unit 1: Pascagoula River drainage, Clarke, Covington, Forrest, George, Greene, Lauderdale, Jackson, Jones, Newton, Perry, Stone, and Wayne Counties, Mississippi.

(i) Unit 1 consists of 487 miles (mi) (783 kilometers (km)) of connected river and stream channels within the Pascagoula River drainage, including:

(A) The Pascagoula River from its confluence with the West Pascagoula River in Jackson County, upstream 63

mi (102 km) to the confluence of the Leaf and Chickasawhay Rivers in George County;

(B) The Big Black/Black Creek from its confluence with the Pascagoula River in Jackson County, upstream 80 mi (129 km) to U.S. Highway 49 Bridge in Forrest County;

(C) The Chickasawhay River from its confluence with the Leaf River just north of Enterprise, Clarke County, upstream 160 mi (257 km) to the

confluence of Okatibbee Creek and Chunky River in Clarke County;

(D) The Chunky River from its confluence with Okatibbee Creek in Clarke County, upstream 21 mi (34 km) to second Highway 80 Crossing in Newton County;

(E) The Leaf River from its confluence with the Chickasawhay River in George County, upstream 119 mi (192 km) to the bridge crossing at U.S. Highway 84 in Covington County;

(F) The Bouie River from its confluence with the Leaf River, upstream 15 mi (24 km) to the confluence of Okatoma Creek, in Forrest County; and

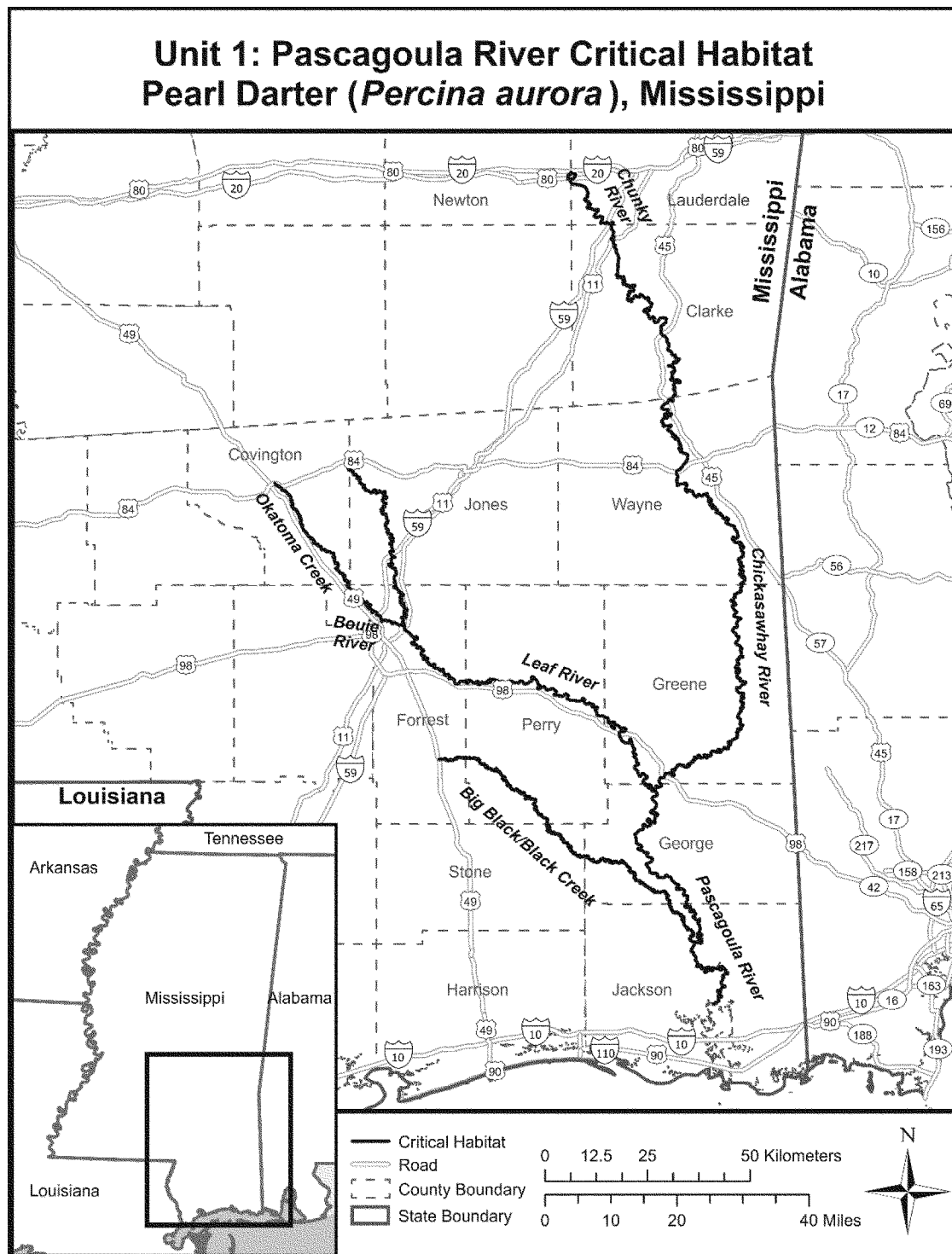
(G) The Okatoma Creek from its confluence with the Bouie River in

Forrest County, upstream 28 mi (45 km) to the bridge crossing at U.S. Highway 84 in Covington County.

(ii) The channel borders (and therefore the stream channel bottoms) in Unit 1 are generally privately owned agricultural or silvicultural lands, with

the exception of 76 mi (122 km) of the Pascagoula River channel border owned and managed by the Mississippi Department of Wildlife, Fisheries, and Parks, and 45 mi (72 km) owned by the U.S. Forest Service.

(iii) Map of Unit 1 follows:



(7) Unit 2: Strong River, Simpson County, Mississippi.

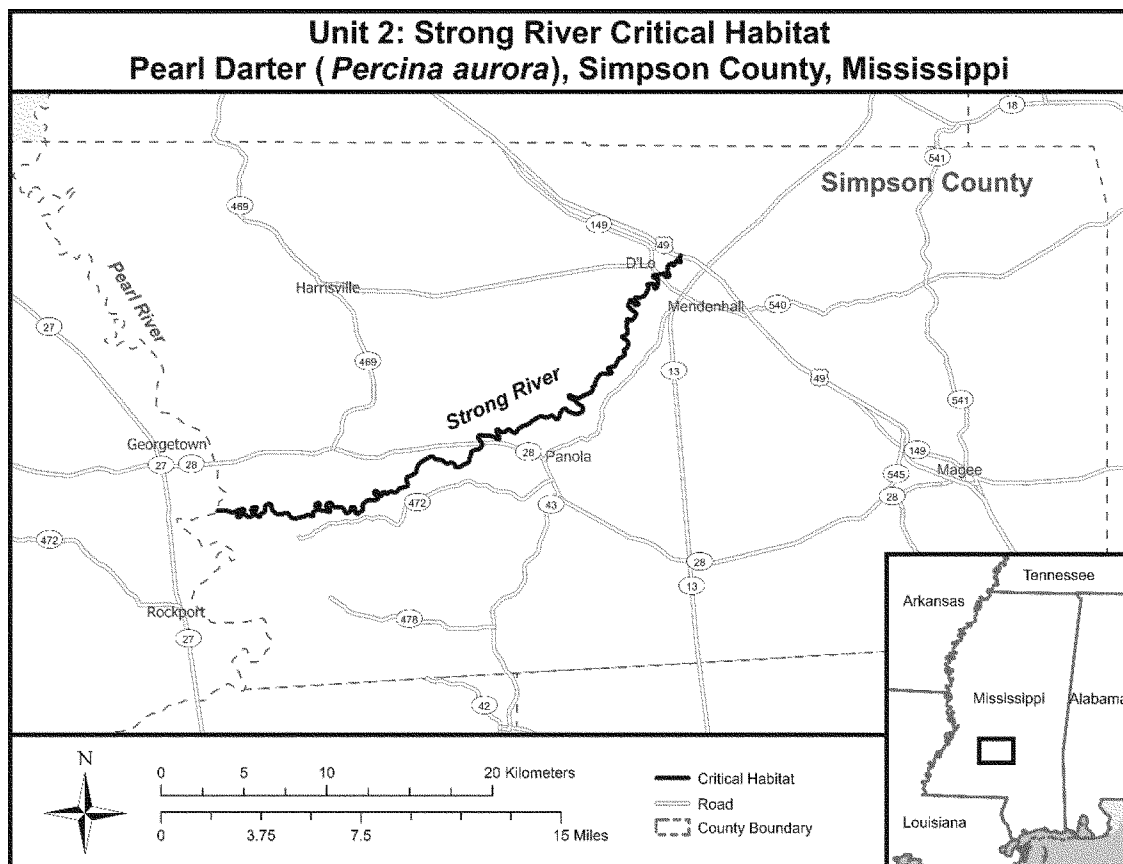
(i) Unit 2 consists of approximately 30 mi (49 km) of the Strong River channel

from its confluence with the Pearl River, upstream to U.S. Highway 49 in

Simpson County. The channel borders (and therefore the stream channel bottoms) in this unit are generally

privately owned agricultural or silvicultural lands, with the exception of a short channel reach (0.39 mi (0.63

km)) owned and managed by the Simpson County Park Commission. (ii) Map of Unit 2 follows:



* * * * *

Madonna Baucum,

*Regulations and Policy Chief, Division of
Policy, Economics, Risk Management, and
Analytics, Joint Administrative Operations,
U.S. Fish and Wildlife Service.*

[FR Doc. 2021-14272 Filed 7-12-21; 8:45 am]

BILLING CODE 4333-15-C

Notices

Federal Register

Vol. 86, No. 131

Tuesday, July 13, 2021

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 8, 2021.

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

Comments regarding these information collections are best assured of having their full effect if received by August 12, 2021. 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.

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

persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: 2022 Census of Agriculture.

OMB Control Number: 0535–0226.

Summary of Collection: The National Agricultural Statistics Service conducts surveys in order to prepare national, state, and county estimates of crop and livestock production, disposition, prices, as well as statistics on related environmental and economic factors. Every five years these survey statistics are benchmarked with a complete census of agricultural producers. This census is required by law under the “Census of Agriculture Act of 1997,” Public Law 105–113 (7 U.S.C. 2204g). It is the primary source of detailed state and county data that provides critical information for the agricultural sector. Without the census, there would be no source of reliable, comparable data throughout the more than 3,000 counties in the 50 States and Puerto Rico. For the outlying areas of American Samoa (AS), the Commonwealth of the Northern Mariana Islands (CNMI), Guam, and the U.S. Virgin Islands (USVI), it is the only source of consistent, comparable agricultural data.

Need and Use of the Information: The data collection for the censuses of agriculture for the 50 states and Puerto Rico will be conducted primarily by mail-out/mail-back procedures (U.S. Postal Service), internet, and with phone and field enumeration for targeted non-respondents. Data collection for Guam, the U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands and American Samoa will be conducted using direct enumeration methods only. The census provides data on the number and types of farms, land use, crop area and selected production, livestock inventory and sales, production contracts, production expenses, farm-related income, and other demographic characteristics. This information will serve as the basis for many agriculturally-based decisions. Census information is used by the Administration, Congress, and the Federal Agencies to formulate and evaluate national agricultural programs and policy. The Department of Agriculture and the Bureau of Economic Analysis use Census data to compile

farm sector economic indicators. State and local governments use Census data in the development of local agricultural programs.

Description of Respondents: Farms; Individuals or households.

Number of Respondents: 4,744,650.

Frequency of Responses: Reporting: Other (Every 5 years).

Total Burden Hours: 3,276,166.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–14829 Filed 7–12–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Clearance for the Stewardship Mapping and Assessment Project (STEW–MAP)

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension without revisions of a currently approved information collection, *Information Collection Clearance for the Stewardship Mapping and Assessment Project (STEW–MAP)*.

DATES: Comments must be received in writing on or before September 13, 2021 to be assured of consideration.

Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Erika Svendsen, USDA Forest Service, NYC Urban Field Station, 431 Walter Reed Rd., Bayside, NY 11359.

Comments also may be submitted via email to: erika.svendsen@usda.gov. Please put “Comments RE: STEW–MAP” in the subject line.

Comments submitted in response to this notice may be made available to the public through relevant websites and upon request. 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 comments that may be made available to the public notwithstanding the inclusion of the routine notice.

The public may inspect the draft supporting statement and/or comments received at USDA Forest Service, NYC Urban Field Station, 431 Walter Reed Road, Bayside, NY 11359 during normal business hours. Visitors are encouraged to call ahead to 718-225-3061 to facilitate entry to the building. The public may request an electronic copy of the draft supporting statement and/or any comments received be sent via return email. Requests should be emailed to erika.svendsen@usda.gov.

FOR FURTHER INFORMATION CONTACT: Erika Svendsen, Northern Research Station, 718-225-3061 extension 102 or erika.svendsen@usda.gov. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Information Collection Clearance for the Stewardship Mapping and Assessment Project (STEW-MAP).

OMB Number: 0596-0240.

Expiration Date of Approval: November 30, 2021.

Type of Request: Extension without revisions.

Abstract: Local environmental stewardship groups are essential for ensuring the vibrancy of natural areas in cities, suburbs, towns, and rural areas, including National Forest lands and the surrounding areas. Natural areas provide a range of benefits and services including storm water management, air pollution removal, urban heat island mitigation, carbon storage, wildlife habitat, recreation opportunities, stress reduction, aesthetic beauty, noise reduction, increased property values, and reduced energy use. The work of civic environmental stewards leverages the efforts of governments in maintaining these resources, especially in lean budget times. Civic stewardship organizations, including nonprofit organizations, faith-based groups, formal and informal community groups, and coalitions, are often involved in environmental stewardship efforts. For example, these groups often plant trees, organize community gardens, offer environment-themed classes, engage

with local officials on behalf of the environment, monitor plants or animals, and clean up nearby parks and/or natural areas. People who do this work are stewards of their local environments, even if they do not normally use the word “steward” or think of what they do as “stewardship.”

The roles of civic environmental stewards and their levels of engagement and commitment are often not understood by land managers and other decision makers. This means that the valuable services they provide may not be recognized and built on to full advantage. In addition, stewards themselves may not be aware of others doing similar work in their area so there may be lost opportunities for collaboration between groups.

The purpose of this research is to gather information on civic stewardship groups and their efforts such as where they work, the types of projects they focus on, and how they are organized. This information will be summarized and made publicly available online for use by policy makers, land managers, environmental professionals, the general public, stewards themselves, and other natural resource management stakeholders.

There are three phases to a STEW-MAP project:

- Phase One (Census) is a census of stewardship groups in the target region, generating a master list of known stewardship groups and their contact information.
- Phase Two (Survey) is a survey which is distributed to all of the organizations identified in Phase One to collect information about what they work on, how their group is structured, where they work, and what other groups they collaborate with.
- Phase Three (Follow-Up Interviews) is follow-up interviews with key responding organizations identified during Phase Two to collect more detailed information about the organizations and their histories.

A primary goal of STEW-MAP is to visualize stewardship activities, which can span across the urban to rural landscape. The geographic information provided by stewardship groups in Phase Two (Survey) will allow the researchers to do a spatial analysis of where stewardship groups are working, identify “gaps” where little to no stewardship is being done, and provide locally relevant geographic information like what kinds of stewardship groups are working in particular places. This geographic information will be displayed on maps to show stewards, local land managers, policy makers, and other interested stakeholders how

stewardship work is distributed across the region with the goal of encouraging collaboration, building innovative partnerships, increasing organizational capacities, and making stewardship efforts more effective.

Information from STEW-MAP will help planners, natural resource decision makers, land managers, and the general public work across property jurisdictions, management regimes and political boundaries to conserve, protect, and manage natural resources effectively. It will also be used to enhance local resource management efforts by helping public officials, land managers, and civic stewards connect to local stewardship groups.

STEW-MAP is being led by Forest Service researchers in partnership with researchers from universities and nongovernmental organizations. The exact makeup of the research team will vary from location to location where STEW-MAP is conducted. The Forest Service Research and Development branch is authorized to conduct basic scientific research to improve the health of forests and rangelands involving State, Federal, Tribal agencies, and private landowners across multiple jurisdictions including in urban areas. The study is aligned with various collaborative approaches to landscape-scale resource management that work across jurisdictions and land-use types, viewing forests as social-ecological systems. Our project goals are also consistent with the Forest Service’s Urban and Community Forestry (UCF) program, which focus on urban forest ecosystems and the role of stewardship and trail connections to parks and public lands that promote health and sustainability for urban residents. This study seeks to identify opportunities for stewardship organizations to better collaborate and, thus, be more effective in the stewardship of natural areas.

Due to local geographical and/or cultural differences, and to meet the needs of any particular collaborative effort, we may tailor the survey and interview questions to accommodate the unique requirements of individual communities.

Affected Public: Representatives from civic environmental stewardship groups, and from State, local, or Tribal Governments.

Estimate of Burden per Response: 15 to 60 minutes.

Estimated Annual Number of Respondents:

Phase One (Census): 600.

Phase Two (Survey): 15,000.

Phase Three (Follow-up Interviews): 300.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 7,925 hours.

Comment is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses if provided, will be a matter of public record. Comments will be summarized and included in the submission request for Office of Management and Budget approval.

Alexander L. Friend,

Deputy Chief, Research & Development.

[FR Doc. 2021-14857 Filed 7-12-21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Directive Publication Notice

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: The USDA Forest Service provides direction to employees through issuances in its Directive System, comprised of the Forest Service Manual and Forest Service Handbooks. The Agency must provide public notice of and opportunity to comment on any directives that formulate standards, criteria, or guidelines applicable to Forest Service programs. Once per quarter, the Agency provides advance notice of proposed and interim directives that will be made available for public comment during the next 3 months and notice of final directives issued in the last 3 months. No directives are planned for publication for public comment between July 1, 2021, and September 30, 2021.

DATES: This notice identifies proposed and interim directives that were published for public comment since

January 1, 2020, and final directives that have been issued since April 1, 2021.

ADDRESSES: Questions or comments may be provided by email to SM.FS.Directives@usda.gov or in writing to 201 14th Street SW, Washington, DC 20250, Attn: Directives and Regulations staff, Mail 1132.

FOR FURTHER INFORMATION CONTACT: Ann Goode at 202-740-6286 or ann.goode@usda.gov. Individuals who use telecommunication devices for the hearing-impaired may call the Federal Relay Service at 800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Daylight Time, Monday through Friday. You may sign up to receive email alerts at <https://www.fs.usda.gov/about-agency/regulations-policies>.

SUPPLEMENTARY INFORMATION:

Proposed or Interim Directives

Consistent with 16 U.S.C. 1612(a) and 36 CFR part 216, Public Notice and Comment for Standards, Criteria and Guidance Applicable to Forest Service Programs, the Forest Service publishes for public notice and comment Agency directives that formulate standards, criteria, or guidelines applicable to Forest Service programs. Agency procedures for providing public notice and opportunity to comment are specified in Forest Service Handbook (FSH) 1109.12, Chapter 30, Providing Public Notice and Opportunity to Comment on Directives.

The Forest Service has no proposed or interim directives planned for publication for public comment from July 1, 2021 to September 30, 2021.

Previously Published Directives That Have Not Been Finalized

The following proposed or interim directives have been published for public comment but not yet finalized:

1. Proposed Forest Service Manual (FSM) 2200, Rangeland Management, Chapters Zero Code; 2210, Rangeland Management Planning; 2220, Management of Rangelands (Reserved); 2230, Grazing Permit System; 2240, Rangeland Improvements; 2250, Rangeland Management Cooperation; and 2270, Information Management and Reports; Forest Service Handbook 2209.13, Grazing Permit Administration Handbook, Chapters 10, Term Grazing Permits; 20, Grazing Agreements; 30, Temporary Grazing and Livestock Use Permits; 40, Livestock Use Permits; 50, Tribal Treaty Authorizations and Special Use Permits; 60, Records; 70, Compensation for Permittee Interests in Rangeland Improvements; 80, Grazing Fees; and 90, Rangeland Management Decision Making; and Forest Service

Handbook 2209.16, Allotment Management Handbook, Chapter 10, Allotment Management and Administration.

2. Interim Forest Service Manual 2719, Special Use Authorizations Involving Storage and Use of Explosives and Magazine Security, and Forest Service Handbook 2709.11, Special Uses Handbook, Chapter 50, Standard Forms and Supplemental Clauses.

3. Forest Service Manual 7700, Travel Management, Chapters Zero and 10, Travel Planning.

4. Forest Service Manual 2400, Timber Management, Chapters Zero, 2430, Commercial Timber Sales; 2440, Designating, Cruising, Scaling, and Accountability; 2450, Timber Sale Contract Administration; and 2460, Uses of Timber Other Than Commercial Timber Sales; Forest Service Handbook 2409.15, Timber Sale Administration, Chapters Zero, 10, Fundamentals of Timber Sale Contracting; 30, Change in Status of Contracts; 50, Specified Transportation Facilities; and 70, Contract Claims and Disputes; Forest Service Handbook 2409.18a, Timber Sale Debarment and Suspension Procedures, Chapters Zero, 10, Non-procurement Debarment and Suspension; and 20, Debarment and Export Violations.

5. Forest Service Manual 3800, Landscape Scale Restoration Program.

6. Forest Service Manual 2700, Special Uses Management, Chapter 40, Vegetation Management Pilot Projects, and Forest Service Handbook 2709.11, Special Uses Handbook, Chapter 50, Standard Forms and Supplemental Clauses.

7. Forest Service Handbook 2709.11, Special Uses Handbook, Chapter 80, Operating Plans and Agreements for Powerline Facilities.

8. Forest Service Manual 2400, Timber Management, Chapter 2420, Timber Appraisal; Forest Service Handbook 2409.19, Renewable Resources Handbook, Chapters 10, Knutson-Vandenberg Sale Area Program Management Handbook; 20, Knutson-Vandenberg Forest and Regional Program Management; 60, Stewardship Contracting; and 80, Good Neighbor Authority.

9. Forest Service Manual 1820, Public Lands Corps and Resource Assistants Program.

10. Forest Service Handbook 5509.11, Chapter 20, Section 21, Small Tracts Act Adjustments.

11. Forest Service Manual 2720, Alaska Region Supplement, Section 2721.53, Outfitting and Guiding Service.

Directives That Have Been Issued Since April 1, 2021

1. Closure of National Forest System Lands to Hunting, Fishing, or Recreational Shooting, Forest Service Handbook 5309.11, Law Enforcement Handbook, Chapter 30, Violations, Section 34. This directive implements, in part, the John D. Dingell Jr. Conservation, Management, and Recreation Act to facilitate access to hunting, fishing and recreational shooting on National Forest System lands. These updates include a greater role for public participation, codification of the national policy that federal lands are open unless closed to hunting, fishing or recreational shooting, and establish a process for temporarily or permanently closing areas on National Forest System lands to hunting, fishing, or recreational shooting. The revisions also include a new definition for emergency closures, which are exempt from the procedural requirements for hunting, fishing, and recreational shooting closure orders. The 30-day comment period for this directive began August 17, 2021, and closed September 16, 2020. Thirty public comments were received, which can be viewed at <https://cara.ecosystem-management.org/Public/ReadingRoom?project=ORMS-2312>. The final directive and a document summarizing public comments and the agency's responses are included in the list of documents below. The final directive was issued April 8, 2021 and can be viewed at https://www.fs.fed.us/im/directives/fsh/5309.11/wo_5309.11_30_Amend-2021-1%20-%20Violations.doc.

2. Providing Notice and Opportunity to Comment on Directives, Forest Service Handbook 1109.12, Directive System, Chapter 30. This directive sets forth direction for providing public notice of and opportunity to comment on Forest Service directives. Specifically, this chapter provides direction for determining whether a directive requires public notice and opportunity for comment, procedures for providing public notice and opportunity to comment on directives, strategies for engaging the public in development of Forest Service directives, interagency and intergovernmental communication, including tribal consultation, consideration of public comments, and finalizing directives.

The comment period for the proposed directive began January 16, 2020, and closed March 16, 2020. The Forest Service received 10 comments on the proposed directive. The comments can

be viewed at <https://cara.ecosystem-management.org/Public/ReadingRoom?project=ORMS-2016>. The directive was designated as significant by the Office of Management and Budget (OMB) and was reviewed by OMB prior to publication for public comment and issuance as a final directive. The final directive was issued April 15, 2021, and can be viewed at [https://www.fs.fed.us/im/directives/fsh/1109.12/1109.12-ch30%20\(216%20Directive\)-final%20\(004\).docx](https://www.fs.fed.us/im/directives/fsh/1109.12/1109.12-ch30%20(216%20Directive)-final%20(004).docx).

3. Operation and Maintenance of Developed Recreation Sites, Forest Service Handbook 2309.13, Chapter 50. This directive establishes a new chapter and revised direction for Forest Service operation and maintenance of developed recreation sites in the Recreation Site Handbook. The new chapter contains direction that was previously set out in Forest Service Manual 2330 and new direction governing national quality standards for Forest Service operation and maintenance of developed recreation sites. The comment period for the directive began July 9, 2020 and ended August 10, 2020. The Forest Service received 5 comments, which can be viewed at <https://cara.ecosystem-management.org/Public/ReadingRoom?project=ORMS-2572>. The final directive was issued June 25, 2021, as amended, and can be viewed at https://www.fs.fed.us/im/directives/fsh/2309.13/wo%202309.13_50_FS%20OM%20of%20Developed%20Recreation%20Sites-PUP.docx.

Dated: July 7, 2021.

Amelia Steed,

Acting Deputy Director, Strategic Planning, Budget, & Accountability.

[FR Doc. 2021-14807 Filed 7-12-21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF COMMERCE
Bureau of Industry and Security**Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting**

The Sensors and Instrumentation Technical Advisory Committee (SITAC) will meet on July 27, 2021, at 1:00 p.m., Eastern Daylight Time, via remote teleconference. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology.

Agenda*Public Session*

1. Welcome and Introductions.
2. Remarks from the Bureau of Industry and Security Management.
3. Industry Presentations.
4. New Business.

Closed Session

5. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at Yvette.Springer@bis.doc.gov no later than July 20, 2021.

A limited number of seats will be available during the public session of the meeting.

Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that the materials be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on February 9, 2021, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public. For more information contact Yvette Springer on (202) 482-2813.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2021-14880 Filed 7-12-21; 8:45 am]

BILLING CODE 3510-JT-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-130]

Certain Walk-Behind Lawn Mowers and Parts Thereof From the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination

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

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing a countervailing duty (CVD) order on certain walk-behind lawn mowers and parts thereof (lawn mowers) from the People's Republic of China (China). In addition, Commerce is amending its final determination with respect to lawn mowers from China to correct a ministerial error.

DATES: Applicable July 13, 2021.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold or Moses Song at (202) 482-1121 or (202) 482-7885, respectively. AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:**Background**

On May 20, 2021, Commerce published its affirmative final determination that countervailable subsidies are being provided to producers and exporters of lawn mowers from China.¹ Respondent company, Ningbo Daye Garden Machinery Co., Ltd. (Ningbo Daye) submitted a timely allegation on the record that Commerce made a ministerial error in the final CVD determination on lawn mowers from China.² Section 705(e) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.224(f) define ministerial errors as errors in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying,

duplication, or the like, and any other type of unintentional error which Commerce considers ministerial. We reviewed the allegation and determined that we made a ministerial error in the final CVD determination on lawn mowers from China. See “Amendment to the Final Determination” section below for further discussion.

On July 6, 2021, the ITC notified Commerce of its affirmative final determination that, pursuant to sections 705(b)(1)(A)(i) and 705(d) of the Act, an industry in the United States is materially injured by reason of subsidized imports of subject merchandise from China.³

Scope of the Order

The products covered by this order are lawn mowers from China. For a complete description of the scope of this order, see the appendix to this notice.

Amendment to the Final Determination

On May 24, 2021, Ningbo Daye submitted a timely ministerial error allegation regarding the *Final Determination*.⁴ Commerce reviewed the record and on June 17, 2021, issued a memorandum acknowledging that the error alleged by Ningbo Daye constituted a ministerial error within the meaning of section 705(e) of the Act and 19 CFR 351.224(f).⁵ Specifically, Commerce found that it had incorrectly transcribed certain data pertaining to Ningbo Daye's outstanding loans, which resulted in an error in the subsidy rate calculation. Pursuant to 19 CFR 351.224(e), Commerce is amending the *Final Determination* to reflect the correction of the ministerial error described in the Ministerial Error Memorandum. Based on the correction, the subsidy rate for Ningbo Daye changed from 14.17 percent to 13.67 percent *ad valorem*. Because the all-others rate is calculated using a weighted average of the individual estimated subsidy rates calculated for mandatory respondents, including Ningbo Daye's *ad valorem* subsidy rate, the all-others rate also changed from 16.29 percent to 15.95 percent.

Countervailing Duty Order

On July 6, 2021, in accordance with section 705(d) of the Act, the ITC notified Commerce of its final

determination that an industry in the United States is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act by reason of subsidized imports of lawn mowers from China.⁶ Therefore, in accordance with section 705(c)(2) of the Act, Commerce is issuing this CVD order. Because the ITC determined that imports of lawn mowers from China are materially injuring a U.S. industry, unliquidated entries of such merchandise from China, entered or withdrawn from warehouse for consumption, are subject to the assessment of CVDs.

Therefore, in accordance with section 706(a) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, CVDs for all relevant entries of lawn mowers from China which are entered, or withdrawn from warehouse, for consumption on or after October 30, 2020, the date of publication of the *Preliminary Determination*,⁷ but will not include entries occurring after the expiration of the provisional measures period and before the publication of the ITC's final injury determination under section 705(b) of the Act, as further described in the “Provisional Measures” section of this notice.

Continuation of Suspension of Liquidation and Cash Deposits

Except as noted in the “Provisional Measures” section of this notice, in accordance with section 706(a)(1) of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of lawn mowers from China. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the net countervailable subsidy rates indicated in the table below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination, CBP must require, at the same time as importers would deposit estimated normal customs duties on subject merchandise, a cash deposit equal to the rates listed in the table below.

¹ See *Certain Walk-Behind Lawn Mowers and Parts Thereof from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 86 FR 27379 (May 20, 2021) (*Final Determination*), and accompanying Issues and Decision Memorandum.

² See Ningbo Daye's Letter, “Certain Walk-Behind Lawn Mowers and Parts Thereof from the People's Republic of China, Case No. C-570-130: Ningbo Daye's Ministerial Error Comments,” dated May 24, 2021 (Ministerial Error Allegations).

³ See ITC's Letter, “Notification of ITC Final Determination,” dated July 6, 2021 (ITC Notification Letter).

⁴ See Ministerial Error Allegations.

⁵ See Memorandum, “Countervailing Duty Investigation of Certain Walk-Behind Lawn Mowers and Parts Thereof from the People's Republic of China: Allegation of Ministerial Error in the Final Determination,” dated June 17, 2021 (Ministerial Error Memorandum) at 1–2.

⁶ See ITC Notification Letter.

⁷ See *Certain Walk-Behind Lawn Mowers and Parts Thereof from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination*, 85 FR 68848 (October 30, 2020) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

Company	Subsidy rate (percent)
Zhejiang Amerisun Technology Co., Ltd	20.98
Ningbo Daye Garden Machinery Co., Ltd ⁸	13.67
All Others	15.95

Provisional Measures

Section 703(d) of the Act states that the suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. Commerce published the *Preliminary Determination* on October 30, 2021.⁹

The provisional measures period, beginning on the date of publication of the *Preliminary Determination*, ended on February 26, 2021. Therefore, in accordance with section 703(d) of the Act and our practice, Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to CVDs, unliquidated entries of lawn mowers from China entered, or withdrawn from warehouse, for consumption after February 26, 2021, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determination in the **Federal Register**.

Notification to Interested Parties

This notice constitutes the CVD order with respect to lawn mowers from China pursuant to section 706(a) of the Act. Interested parties can find a list of CVD orders currently in effect at <http://enforcement.trade.gov/stats/iastats1.html>.

This amended final determination and order is issued and published in accordance with sections 705(d) and 706(a) of the Act and 19 CFR 351.211(b) and 351.224(e).

Dated: July 8, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Order

The merchandise covered by this order consists of certain rotary walk-behind lawn

mowers, which are grass-cutting machines that are powered by internal combustion engines. The scope of this order covers certain walk-behind lawn mowers, whether self-propelled or non-self-propelled, whether finished or unfinished, whether assembled or unassembled, and whether containing any additional features that provide for functions in addition to mowing.

Walk-behind lawn mowers within the scope of this order are only those powered by an internal combustion engine with a power rating of less than 3.7 kilowatts. These internal combustion engines are typically spark ignition, single or multiple cylinder, air cooled, internal combustion engines with vertical power take off shafts with a maximum displacement of 196cc. Walk-behind lawn mowers covered by this scope typically must be certified and comply with the Consumer Products Safety Commission Safety Standard For Walk-Behind Power Lawn Mowers under 16 CFR part 1205. However, lawn mowers that meet the physical descriptions above, but are not certified under 16 CFR part 1205 remain subject to the scope of this order.

The internal combustion engines of the lawn mowers covered by this scope typically must comply with and be certified under Environmental Protection Agency air pollution controls title 40, chapter I, subchapter U, part 1054 of the Code of Federal Regulations standards for small non-road spark-ignition engines and equipment. However, lawn mowers that meet the physical descriptions above but that do not have engines certified under 40 CFR part 1054 or other parts of subchapter U remain subject to the scope of this order.

For purposes of this order, an unfinished and/or unassembled lawn mower means, at a minimum, a sub-assembly comprised of an engine and a cutting deck shell attached to one another. A cutting deck shell is the portion of the lawn mower—typically of aluminum or steel—that houses and protects a user from a rotating blade. Importation of the subassembly whether or not accompanied by, or attached to, additional components such as a handle, blade(s), grass catching bag, or wheel(s) constitute an unfinished lawn mower for purposes of this order. The inclusion in a third country of any components other than the mower subassembly does not remove the lawn mower from the scope. Lawn mowers that meet the physical description above are covered by the scope of this order regardless of the origin of its engine, unless such lawn mowers contain an engine that is covered by the scope of the antidumping and countervailing duty orders on certain vertical shaft engines between 99cc and up to 225cc, and parts thereof (small vertical engines) from China. If the antidumping or countervailing duty orders on small vertical engines from China are terminated, the lawn mowers containing small vertical engines from China will be covered by the scope of this order.

The lawn mowers subject to this order are typically at subheading: 8433.11.0050. Lawn mowers subject to this order may also enter under Harmonized Tariff Schedule of the United States (HTSUS) 8407.90.1010 and

8433.90.1090. The HTSUS subheadings are provided for convenience and customs purposes only, and the written description of the merchandise under this order is dispositive.

[FR Doc. 2021–14839 Filed 7–12–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–129, A–552–830]

Certain Walk-Behind Lawn Mowers and Parts Thereof From the People's Republic of China and the Socialist Republic of Vietnam: Antidumping Duty Orders

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

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing antidumping duty orders on certain walk-behind lawn mowers and parts thereof (lawn mowers) from the People's Republic of China (China) and the Socialist Republic of Vietnam (Vietnam).

DATES: Applicable July 13, 2021.

FOR FURTHER INFORMATION CONTACT: Marc Castillo or Fred Baker at 202–482–0519 and 202–482–2924, respectively (China), and Frank Schmitt or Mark Flessner at 202–482–4880 and 202–482–6312, respectively (Vietnam); AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 20, 2021, Commerce published its affirmative final determinations in the less-than-fair-value (LTFV) investigations of lawn mowers from China and Vietnam.¹ On July 6, 2021, the ITC notified Commerce of its final determinations, pursuant to section 735(d) of the Tariff Act of 1930, as amended (the Act), that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of LTFV imports of lawn mowers from

¹ See *Certain Walk-Behind Lawn Mowers and Parts Thereof from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value*, 86 FR 27384 (May 20, 2021); see also *Certain Walk-Behind Lawn Mowers and Parts Thereof from the Socialist Republic of Vietnam: Final Affirmative Determination of Sales at Less Than Fair Value*, 86 FR 27382 (May 20, 2021).

⁸ Commerce determined that, pursuant to 19 CFR 351.525(b)(6)(vi), cross-ownership exists between Ningbo Daye Garden Machinery Co. Ltd. and Zhejiang Jingaye Holdings Ltd.

⁹ See *Preliminary Determination*.

China, and is threatened with material injury by reason of LTFV imports of lawn mowers from Vietnam.²

Scope of the Orders

The products covered by these orders are lawn mowers from China and Vietnam. For a complete description of the scope of these orders, see the appendix to this notice.

Antidumping Duty Orders

On July 6, 2021, in accordance with sections 735(b)(1)(A)(i)–(ii) and 735(d) of the Act, the ITC notified Commerce of its final determinations in these investigations, in which it found that an industry in the United States is materially injured by reason of imports of lawn mowers from China, and is threatened with material injury by reason of imports of lawn mowers from Vietnam.³ Therefore, in accordance with section 735(c)(2) of the Act, we are issuing these antidumping duty orders. Because the ITC determined that imports of lawn mowers from China are materially injuring a U.S. industry and imports of lawn mowers from Vietnam are threatening material injury to a U.S. industry, unliquidated entries of such merchandise from China and Vietnam, which are entered, or withdrawn from warehouse, for consumption are subject to the assessment of antidumping duties. Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of lawn mowers from China and Vietnam.

With respect to China, antidumping duties will be assessed on unliquidated entries of lawn mowers from China entered, or withdrawn from warehouse, for consumption on or after December 30, 2020, the date of publication of the *China Preliminary Determination*.⁴

With respect to Vietnam, because the ITC's final determination is based on the threat of material injury, other than threat of material injury described in section 736(b)(1) of the Act, duties shall be assessed on subject merchandise

entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination, pursuant to section 736(b)(2) of the Act. In addition, section 736(b)(2) of the Act requires CBP to release any bond or other security, and refund any cash deposit made of estimated antidumping duties posted since Commerce's preliminary antidumping duty determination.

Accordingly, Commerce will direct CBP to terminate the suspension of liquidation for entries of lawn mowers from Vietnam entered, or withdrawn from warehouse, for consumption prior to the publication of the ITC final determination in the **Federal Register**. Commerce will also instruct CBP to refund any cash deposits made with respect to entries of lawn mowers from Vietnam entered, or withdrawn from warehouse, for consumption on or after December 30, 2020, (the date of publication of the *Vietnam Preliminary Determination* ⁵), but before June 28, 2021 (the date suspension of liquidation was discontinued in accordance with section 733(d) of the Act).

Suspension of Liquidation

In accordance with section 736 of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of lawn mowers from China, which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's final determination in the **Federal Register**. Commerce will also instruct CBP to reinstitute the suspension of liquidation of lawn mowers from Vietnam, effective the date of publication of the ITC's final determination in the **Federal Register**, and to assess, upon further instruction by Commerce, pursuant to section 736(a)(1) of the Act, antidumping duties for each entry of the subject merchandise equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the estimated weighted-average dumping

margins indicated in the tables below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determinations, CBP will require, at the same time as importers would normally deposit estimated duties on subject merchandise, a cash deposit equal to the rates listed below.

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise request that Commerce extend the four-month period to no more than six months. At the request of exporters that account for a significant proportion of lawn mowers from China and Vietnam, Commerce extended the four-month period to six months in each of these investigations. Commerce published the preliminary determinations in these investigations on December 30, 2020.⁶

The extended provisional measures period, beginning on the date of publication of the *Preliminary Determinations*, ended on June 27, 2021. Therefore, in accordance with section 733(d) of the Act and our practice,⁷ Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of lawn mowers from China and Vietnam entered, or withdrawn from warehouse, for consumption after June 27, 2021, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final affirmative injury determinations in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determinations in the **Federal Register**.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

China

² See ITC Notification Letter, Investigation Nos. 701-TA-648 731-TA-1521-1522 (Final), dated July 6, 2021.

³ *Id.*

⁴ See *Certain Walk-Behind Lawn Mowers and Parts Thereof from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional*

Measures, 85 FR 86529 (December 30, 2020) (*China Preliminary Determination*).

⁵ See *Certain Walk-Behind Lawn Mowers and Parts Thereof from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 85 FR 86534 (December 30, 2020) (*Vietnam Preliminary Determination*).

⁶ See *China Preliminary Determination*; see also *Vietnam Preliminary Determination*.

⁷ See, e.g., *Certain Corrosion-Resistant Steel Products from India, India, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR 48390, 48392 (July 25, 2016).

Producer	Exporter	Estimated weighted-average dumping margin (percent)	Cash deposit rates (adjusted for subsidy offsets) (percent)
Ningbo Daye Garden Machinery Co., Ltd	Ningbo Daye Garden Machinery Co., Ltd	98.73	88.14
Chongqing Dajiang Power Equipment Co., Ltd	Chongqing Dajiang Power Equipment Co., Ltd	98.73	88.17
MTD Machinery (Suzhou) Co., Ltd	MTD Machinery (Suzhou) Co., Ltd	98.73	88.17
Qianjiang Group Wenling Jennfeng Industry, Inc	Sumec Hardware & Tools Co., Ltd	98.73	88.17
Sumec Hardware & Tools Co., Ltd	Sumec Hardware & Tools Co., Ltd	98.73	88.17
Zhejiang KC Mechanical & Electrical Co., Ltd	Sumec Hardware & Tools Co., Ltd	98.73	88.17
Zhejiang Dobest Power Tools Co., Ltd	Zhejiang Amerisun Technology Co., Ltd	98.73	88.17
Zhejiang Dobest Power Tools Co., Ltd	Zhejiang Dobest Power Tools Co., Ltd	98.73	88.17
Zhejiang YAT Electrical Appliance Co., Ltd	Zhejiang YAT Electrical Appliance Co., Ltd	98.73	88.17
Zhejiang Zhongjian Technology Co., Ltd	Zhejiang Zhongjian Technology Co., Ltd	98.73	88.17
China-Wide Entity		274.29	263.75

Vietnam

Producer	Exporter	Estimated weighted-average dumping margin (percent)
Ducar Technology Co., Ltd	Ducar Technology Co., Ltd	148.35
Vietnam-Wide Entity		176.37

Notification to Interested Parties

This notice constitutes the antidumping duty orders with respect to lawn mowers from China and Vietnam pursuant to section 736(a) of the Act. Interested parties can find a list of antidumping duty orders currently in effect at <http://enforcement.trade.gov/stats/iastats1.html>.

These antidumping duty orders are published in accordance with sections 735(e) and 736(a) of the Act, and 19 CFR 351.224(e) and 19 CFR 351.211(b).

Dated: July 8, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix—Scope of the Orders

The merchandise covered by these orders consists of certain rotary walk-behind lawn mowers, which are grass-cutting machines that are powered by internal combustion engines. The scope of these orders covers certain walk-behind lawn mowers, whether self-propelled or non-self-propelled, whether finished or unfinished, whether assembled or unassembled, and whether containing any additional features that provide for functions in addition to mowing.

Walk-behind lawn mowers within the scope of these orders are only those powered by an internal combustion engine with a power rating of less than 3.7 kilowatts. These internal combustion engines are typically spark ignition, single or multiple cylinder, air cooled, internal combustion engines with vertical power take off shafts with a maximum displacement of 196cc. Walk-behind lawn mowers covered by this scope

typically must be certified and comply with the Consumer Products Safety Commission Safety Standard For Walk-Behind Power Lawn Mowers under 16 CFR part 1205. However, lawn mowers that meet the physical descriptions above, but are not certified under 16 CFR part 1205 remain subject to the scope of these orders.

The internal combustion engines of the lawn mowers covered by this scope typically must comply with and be certified under Environmental Protection Agency air pollution controls title 40, chapter I, subchapter U, part 1054 of the Code of Federal Regulations standards for small non-road spark-ignition engines and equipment. However, lawn mowers that meet the physical descriptions above but that do not have engines certified under 40 CFR part 1054 or other parts of subchapter U remain subject to the scope of these orders.

For purposes of these orders, an unfinished and/or unassembled lawn mower means, at a minimum, a sub-assembly comprised of an engine and a cutting deck shell attached to one another. A cutting deck shell is the portion of the lawn mower—typically of aluminum or steel—that houses and protects a user from a rotating blade. Importation of the subassembly whether or not accompanied by, or attached to, additional components such as a handle, blade(s), grass catching bag, or wheel(s) constitute an unfinished lawn mower for purposes of these orders. The inclusion in a third country of any components other than the mower subassembly does not remove the lawn mower from the scope. Lawn mowers that meet the physical description above are covered by the scope of these orders regardless of the origin of its engine, unless such lawn mowers contain an engine that is covered by the scope of the antidumping and

countervailing duty orders on certain vertical shaft engines between 99cc and up to 225cc, and parts thereof (small vertical engines) from China. If the antidumping or countervailing duty orders on small vertical engines from China are terminated, the lawn mowers containing small vertical engines from China will be covered by the scope of these orders.

The lawn mowers subject to these orders are typically at subheading: 8433.11.0050. Lawn mowers subject to these orders may also enter under Harmonized Tariff Schedule of the United States (HTSUS) 8407.90.1010 and 8433.90.1090. The HTSUS subheadings are provided for convenience and customs purposes only, and the written description of the merchandise under these orders is dispositive.

[FR Doc. 2021-14840 Filed 7-12-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-427-831]

Methionine From France: Antidumping Duty Order

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

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing an antidumping

duty (AD) order on methionine from France.

FOR FURTHER INFORMATION CONTACT:

Zachary Shaykin, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2638.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i)(1) of the Tariff Act of 1930, as amended (the Act), on May 17, 2021, Commerce published its *Final Determination* in the less-than-fair-value (LTFV) investigation of imports of methionine from France in which it found that sales of methionine from France were at LTFV and that critical circumstances existed for the mandatory respondent in the investigation but did not exist for all other producers and exporters.¹ On June 30, 2021, the ITC notified Commerce of its final affirmative determination that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act, by reason of the LTFV imports of methionine from France, and its determination that critical circumstances do not exist with respect to methionine from France subject to Commerce's partial affirmative critical circumstances determination on May 17, 2021.²

Scope of the Order

The product covered by this order is methionine from France. For a full description of the scope of the order, see the appendix to this notice.

Antidumping Duty Order

On June 30 2021, in accordance with sections 735(b)(1)(A)(i) and 735(d) of the Act, the ITC notified Commerce of the ITC Final Determinations that an industry in the United States is materially injured by reason of imports of methionine from France and its determination that critical circumstances do not exist with respect to imports of subject merchandise from France that are subject to Commerce's affirmative critical circumstances finding. Therefore, in accordance with section 735(c)(2) of the Act, we are issuing this AD order on methionine from France. Because Commerce has

determined that sales of methionine from France were made at LTFV, and the ITC determined that imports of methionine from France are materially injuring the U.S. industry, unliquidated entries of such merchandise from France entered, or withdrawn, for consumption are subject to the assessment of antidumping duties.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce intends to direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise for all relevant entries of methionine from France. As further described below, antidumping duties will be assessed on unliquidated entries of methionine entered, or withdrawn from warehouse, for consumption, on or after March 4, 2021, the date of publication of the *Preliminary Determination*,³ but will not include entries occurring after the expiration of the provisional measures period and before publication of the ITC's final injury determination, as further described below.

Continuation of Suspension of Liquidation

Except as noted in the "Provisional Measures" section of this notice, in accordance with section 735(c)(1)(B) of the Act, Commerce intends to instruct CBP to continue to suspend liquidation on all relevant entries of methionine from France. These instructions suspending liquidation will remain in effect until further notice. Pursuant to 735(c)(1)(B) of the Act and 19 CFR 351.210(d), Commerce also intends to instruct CBP to require cash deposits equal to the estimated weighted-average dumping margins indicated in the table below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination,⁴ CBP must require, at the same time as importers would normally deposit estimated customs duties on subject merchandise, a cash deposit equal to the rates listed in the table below. The all-others rate applies to producers and exporters not specifically listed, as appropriate.

³ See *Methionine From France: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances*, 86 FR 12627 (March 4, 2021) (*Preliminary Determination*).

⁴ See *Methionine from France* (Inv. No. 731-TA-1534 (*Final*)), 86 FR 35826 (July 7, 2021) (*ITC Final Determination*).

Critical Circumstances

With regard to instances in which entries of subject merchandise were produced and exported by Adisseo France S.A.S. and Commentry (collectively, Adisseo), or produced by Adisseo and exported by a company not specified in the table below, within 90 days prior to the publication of the *Preliminary Determination*, then, pursuant to section 735(c)(1)(B)(ii) of the Act, Commerce had instructed CBP to require a cash deposit for such entries of subject merchandise at a rate equal to the estimated weighted-average dumping margin established for Adisseo.

However, with regard to the ITC's negative critical circumstances determination on imports of methionine from France, we will instruct CBP to lift suspension and to refund all cash deposits made to secure the payment of estimated antidumping duties with respect to entries of the subject merchandise attributed to all parties entered, or withdrawn from warehouse, for consumption on or after December 4, 2020 (*i.e.*, 90 days prior to the date of the publication of the *Preliminary Determination*), but before March 4, 2021 (*i.e.*, the date of publication of the *Preliminary Determination*).

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Exporter or producer	Estimated weighted-average dumping margin (percent)
Adisseo France S.A.S. and Commentry	43.82
All Others	16.17

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise request that commerce extend the four-month period to no more than six months. For this investigation, Commerce decided not to extend the four-month period to six months. Commerce published the *Preliminary Determination* in this investigation on March 4, 2021.⁵

The provisional measures period, beginning on the date of publication of

⁵ *Id.*

¹ See *Methionine from France: Final Determination of Sales at Less Than Fair Value and Final Partial Determination of Critical Circumstances*, 86 FR 26697 (May 17, 2021) (*Final Determination*).

² See ITC's Letter, ITC Notification, dated June 30, 2021.

the preliminary determination, ended on July 1, 2021. Therefore, in accordance with section 733(d) of the Act and our practice, Commerce will instruct CBP to terminate the suspension of liquidation, to refund all cash deposits for estimated antidumping duties, and to liquidate, without regard to antidumping duties, unliquidated entries of methionine from France entered, or withdrawn from warehouse, for consumption after July 1, 2021, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final affirmative injury determination in the **Federal Register** (*i.e.*, through July 6, 2021).⁶ Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determination in the **Federal Register** (*i.e.*, July 7, 2021).

Notification to Interested Parties

This notice constitutes the AD order with respect to methionine from France, pursuant to section 736(a) of the Act. Interested parties can find a list of AD orders currently in effect at <http://enforcement.trade.gov/stats/enfstats1.html>.

This order is published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: July 8, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Order

The merchandise covered by this order is methionine and dl-Hydroxy analogue of dl-methionine, also known as 2-Hydroxy 4-(Methylthio) Butanoic acid (HMTBa), regardless of purity, particle size, grade, or physical form. Methionine has the chemical formula $C_5H_{11}NO_2S$, liquid HMTBa has the chemical formula $C_5H_{10}O_3S$, and dry HMTBa has the chemical formula $(C_5H_9O_3S)_2Ca$.

Subject merchandise also includes methionine processed in a third country including, but not limited to, refining, converting from liquid to dry or dry to liquid form, or any other processing that would not otherwise remove the merchandise from the scope of this order if performed in the country of manufacture of the in-scope methionine or dl-Hydroxy analogue of dl-methionine.

The scope also includes methionine that is commingled (*i.e.*, mixed or combined) with methionine from sources not subject to this order. Only the subject component of such commingled products is covered by the scope of this order.

Excluded from this order is United States Pharmacopoeia (USP) grade methionine. In

order to qualify for this exclusion, USP grade methionine must meet or exceed all of the chemical, purity, performance, and labeling requirements of the United States Pharmacopeia and the National Formulary for USP grade methionine.

Methionine is currently classified under subheadings 2930.40.00.00 and 2930.90.46.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Methionine has the Chemical Abstracts Service (CAS) registry numbers 583–91–5, 4857–44–7, 59–51–8 and 922–50–9. While the HTSUS subheadings and CAS registry number are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

[FR Doc. 2021–14893 Filed 7–12–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of an open meeting of a federal advisory committee.

SUMMARY: This notice sets forth the schedule and proposed topics for a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for Monday, August 2, 2021; Tuesday, August 3, 2021; and Wednesday, August 4, 2021; from 1:00 p.m. to 4:00 p.m. Eastern Daylight Time (EDT). The deadline for members of the public to register to participate, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on Friday, July 23, 2021.

ADDRESSES: The meeting will be held virtually via Webex. Requests to register to participate (including to speak or for auxiliary aids) and any written comments should be submitted via email to Ms. Victoria Yue, Office of Energy & Environmental Industries, International Trade Administration, at Victoria.yue@trade.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Victoria Yue, Office of Energy & Environmental Industries, International Trade Administration (Phone: 202–482–3492; email: Victoria.yue@trade.gov).

SUPPLEMENTARY INFORMATION: The meeting will take place on Monday, August 2, 2021; Tuesday, August 3, 2021; and Wednesday, August 4, 2021; from 1:00 p.m. to 4:00 p.m. EDT. The

general meeting is open to the public, and time will be permitted for public comment on Wednesday, August 3, 2021, from 3:40 p.m. to 4:00 p.m. EDT. Members of the public seeking to attend the meeting are required to register in advance. Those interested in attending must provide notification by Friday, July 23, 2021, at 5:00 p.m. EDT, via the contact information provided above. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at Victoria.Yue@trade.gov or (202) 482–3492 no less than one week prior to the meeting. Requests received after this date will be accepted, but it may not be possible to accommodate them.

Written comments concerning ETTAC affairs are welcome any time before or after the meeting. To be considered during the meeting, written comments must be received by Friday, July 23, 2021, at 5:00 p.m. EDT to ensure transmission to the members before the meeting. Minutes will be available within 30 days of this meeting.

Topics to be considered: During the August 2–4 meeting, which is the first meeting of the current charter term, the Committee, with officials from the U.S. Department of Commerce and other agencies, will discuss major issues affecting the competitiveness of the U.S. environmental technologies industry, determine subcommittee structure, and provide consultation on ETTAC leadership. An agenda will be made available one week prior to the meeting upon request to Victoria Yue.

Background: The ETTAC is mandated by Section 2313(c) of the Export Enhancement Act of 1988, as amended, 15 U.S.C. 4728(c), to advise the Environmental Trade Working Group of the Trade Promotion Coordinating Committee, through the Secretary of Commerce, on the development and administration of programs to expand U.S. exports of environmental technologies, goods, services, and products. The ETTAC was most recently re-chartered through August 15, 2022.

Dated: July 7, 2021.

Man Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2021–14812 Filed 7–12–21; 8:45 am]

BILLING CODE 3510–DR–P

⁶ See ITC Final Determination.

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648–XB205]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 77 HMS Hammerhead Shark Stock Identification (ID) Webinar 2.

SUMMARY: The SEDAR 77 assessment of the Atlantic stock of hammerhead sharks will consist of a stock ID process, data webinars/workshop, a series of assessment webinars, and a review workshop.

DATES: The SEDAR 77 HMS Hammerhead Shark Stock ID Webinar 2 has been scheduled for Tuesday August 10, 2021, from 12 p.m. until 3 p.m. ET.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Registration is available online at: <https://attendee.gotowebinar.com/register/1490341148333434635>.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; www.sedarweb.org.

FOR FURTHER INFORMATION CONTACT:

Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: Kathleen.Howington@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates

the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 77 HMS Hammerhead Shark Stock ID Webinar 2 are as follows:

- Participants will use review genetic studies, growth patterns, and any other relevant information on hammerhead shark stock structure.
- Participants will make final recommendations on biological stock structure and define the unit stock or stocks to be addressed through this assessment.

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

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

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

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

Dated: July 8, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–14850 Filed 7–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648–XB221]

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 (ASMFC) Summer Flounder, Scup, and Black Sea Bass Management Board.

DATES: The meeting will be held on Wednesday August 4, 2021, from 10:15 a.m. to 12:15 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Details on the proposed agenda, webinar listen-in access, and any meeting materials will be posted at www.mafmc.org/meetings.

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 Council and the ASMFC's Summer Flounder, Scup, and Black Sea Bass Management Board will reconsider revisions to the commercial black sea bass state allocations previously approved through the Council's Black Sea Bass Commercial State Allocation Amendment and the Commission's Addendum XXXIII. 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 these meetings. 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 Kathy Collins at the Council Office, (302) 526-5253, at least 5 days prior to the meeting date.

Dated: July 7, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-14783 Filed 7-12-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB224]

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice for request of proposals for Ageing Study on Gulf of Mexico Gray Triggerfish.

SUMMARY: The Gulf of Mexico Fishery Management Council is requesting proposals from qualified contractors to organize and conduct an Expanded Sampling and Ageing Study on Gulf of Mexico Gray Triggerfish.

DATES: This will be a 24-month project and a maximum \$250,000 is available to fund the work. Proposal Submission Deadline: August 13, 2021.

ADDRESSES: *Council address:* Gulf of Mexico Fishery Management Council, 4701 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348-1630.

FOR FURTHER INFORMATION CONTACT: Dr. John Froeschke, Deputy Director, Gulf of Mexico Fishery Management Council; john.froeschke@gulfcouncil.org; telephone: (813) 348-1630.

SUPPLEMENTARY INFORMATION:

Proposal Submission Deadline Friday, August 13, 2021

The Gulf of Mexico Fishery Management Council (Council) seeks a highly-qualified contractor to organize and conduct an ageing study on Gulf of Mexico (Gulf) gray triggerfish, *Balistes capricus*. The Term of Contract is 24 months and Maximum Funding Available for Work is \$250,000. The contractor is tasked with evaluating and proposing new techniques to efficiently sample, process, and utilize different ageing structures (*i.e.*, spines and otoliths) for gray triggerfish in the Gulf. Proposal applicants are encouraged to develop work plans to collaborate with state and federal partners to collect representative samples across a range of age classes. Typically, the various Gulf state and federal creel and port samplers would be able to contribute to this work; however, otoliths are not currently taken at dockside intercepts under current sample collection protocols. Sampling gray triggerfish otoliths that are small, fragile, and difficult to extract may require obtaining filleted carcasses (*i.e.*, racks) from fishery-dependent intercepts. If additional samples are necessary, the proposal may consider an effective method for field collection of gray triggerfish otoliths and dorsal spines.

Gray triggerfish have historically been aged by counting translucent zones in the first dorsal spine since gray triggerfish otoliths are small, fragile, and difficult to extract. During the Data/Assessment workshop deliberations for SEDAR 62, it was noted that a study applying bomb radiocarbon validation to compare spine and otolith ages routinely resulted in lower age estimates from spines versus otoliths, and called into question the reliability of growth estimates derived from spine-based ages (Patterson et al. 2019: SEDAR62-WP-17).

Background

During its January 2021 meeting, the Council identified unspent Council funds in 2020. These unspent funds were primarily due to limited travel during the COVID-19 pandemic. The Council is considering funding a research study, on the ageing of gray triggerfish, that could be completed, available, and contributory to the scheduled SEDAR Research Track assessment of Gulf gray triggerfish to begin in 2024. The last assessment for Gulf gray triggerfish (SEDAR 62) was terminated because of irreconcilable data issues, with ageing of gray triggerfish being an outstanding concern.

Gray triggerfish have historically been aged by counting translucent zones in the first dorsal spines since gray triggerfish otoliths tend to be small, fragile, and difficult to extract. Allman *et al.* (2016) conducted an age validation study of gray triggerfish spines that revealed two peaks in translucent zone formation, which was interpreted as a doublet pattern (two closely spaced translucent zones) representing a single year in the life. However, during workshop deliberations for SEDAR 62, it was noted that a study applying bomb radiocarbon validation to compare spine and otolith ages resulted in otolith ages better aligning with known regional coral and otolith carbon-14 values compared to spines, which under-aged known records. Whereas, the comparison of vertebra versus otolith-derived ages indicated a close agreement (Patterson *et al.* 2019: SEDAR62-WP-17).

Shervette *et al.* (2021), conducted a study on gray triggerfish in Ghana and U.S. South Atlantic that compared ageing of spines and otoliths. They also developed a methodology for removing the otoliths from gray triggerfish. Whole otoliths were submerged in water and read against a black background with magnified stereoscope, and then each opaque zone was counted. Spines were also read and fish were aged by counting the number of translucent zones in the spine section. Two independent readers with ageing experience of 8 years +, read the otoliths and spines. This study found age estimates for spines ranged from 1 to 8 years and for otoliths 3 to 13 years. An age bias plot indicating a potential ageing bias starting at age-3 between spines and otoliths of gray triggerfish. Therefore, the Council is interested in funding an age study for Gulf gray triggerfish to reconcile ageing differences in hard parts. The Council also seeks expert advice from funded work to determine whether it is possible to develop an algorithm to convert spine-based ages to the more accurate otolith-based ages for Gulf gray triggerfish.

Scope of Work

The contractor will be responsible for all data products outlined below and is encouraged to contribute additional products and suggestions in the proposal for this work. The selected contractor is also responsible for a mid-term project summary report and a presentation of the final results to the Scientific and Statistical Committees and the Council. The proposed scope of work should include the following:

- Evaluating and proposing new techniques to efficiently sample, process, and utilize different ageing structures (*i.e.*, spines and otoliths) for gray triggerfish in the Gulf.

- Clearly define how representative gray triggerfish samples will be obtained from various fleets (*i.e.*, private recreational, for-hire, and commercial) and/or fishery-independent survey samples with the goal of constructing age-length keys from otolith-based ages. The proposal should include the methodology of the age validation work proposed with a clear rationale for that work, such as literature cited and the anticipated sample sizes of fish by age class (0–14 years).

- Typically, the various Gulf state and federal creel and port samplers would be able to contribute to this work; however, otoliths are not currently taken at dockside intercepts under current sample collection protocols. Thus, proposal applicants are encouraged to develop work plans to collaborate with state and federal partners to collect representative samples across a range of age classes.

- The proposal should include detailed methodology for extracting and processing otoliths and spines and a clear rationale for that scope, and the anticipated sample sizes of fish by age class.

- Compare gray triggerfish ages from otoliths and spines to determine whether it is possible to develop an algorithm to convert spine-based ages to the more accurate otolith-based ages. Describe the variance about these estimates for the conversion algorithm as appropriate.

- Proposals should provide information and rationale for the consideration of seasonal growth increment pattern validation.

Results and outcomes from this work will be provided to the Council and National Marine Fisheries Southeast Fisheries Science Center (SEFSC).

Application Process

Contractor Qualifications: The successful applicant or applicant team will have demonstrable experience in marine ecology.

How to Apply: Applicants should submit a proposal to Gulf of Mexico Fishery Management Council by email (rfp.graytriggerfish@gulfcouncil.org) by 11:59 p.m. on August 13, 2021. Additional information including funding specifications can be obtained through inquiry to this email address. Proposals should include the following elements:

Executive Summary: A summary of the work proposed, including a brief

summary of the applicant's qualifications.

Proposed Scope of Work: See bulleted list above.

Qualifications of Applicant: A summary of the qualifications of the applicant and other team members, if applicable. A curriculum vitae should be included for each individual who is expected to work on the project.

Proposed Budget: A detailed budget, including the basis for the charges (*e.g.*, hourly rates, fixed fees, approved federally negotiated overhead rate and other costs consistent with federally allowable costs for sub-contractors).

Proposed Timeline: A detailed timeline of field and laboratory collections, processing of samples, data analysis, and mid-term and final reports should be provided.

Letters of Support: Letters demonstrating collaboration with state and federal partners and fishermen to obtain adequate samples across age classes are highly encouraged.

Applicant References: Names, titles, full addresses, email addresses, and phone numbers for three clients for whom the applicant has provided similar services to those requested or are familiar with the applicant's work and the quality of the applicant's work products.

Proposal Evaluation Criteria and Next Steps

Proposals will be evaluated based on methodology and scope outlined in the proposed work plan. An ability to deliver, in a timely manner, a quality work product as determined by qualifications including prior experience, references, budget, and timelines is paramount. The Council may request additional information as deemed necessary or negotiate modifications prior to providing support for a proposal. Once a proposal is selected for funding, a formal contract will be provided to the applicants.

Disclaimer

1. This project is being funded by federal funding authorized under the Magnuson-Stevens Fishery Conservation and Management Act through NOAA Fisheries Service and the Gulf of Mexico Fishery Management Council NOAA award number NA20NMF4410011. Compliance with the Magnuson-Stevens Fishery Conservation and Management Act (Pub. L. 104–208 as amended), the current requirements of the Federal Office of Management and Budget, the Department of Commerce financial assistance standard terms and conditions, the National Oceanic and

Atmospheric financial assistance administrative terms, all special award conditions specific to this award and all parts of the Uniform Guidance at Title 2 of the Code of Federal Regulations must be maintained.

2. The contractor is responsible for all costs conducting the work and presenting the final results to the Scientific and Statistical Committees and Council.

3. Proposals and their accompanying documentation will not be returned, but retained as part of the Councils administrative documents.

4. All applicants included in the proposal must disclose any conflicts of interest and/or pending civil/criminal/fishery legal actions.

5. The Council reserves the right to accept or reject any or all applications received, negotiate with all qualified applicants, cancel or modify this request for proposals in part or in its entirety, or change the application guidelines, when it is in the best interests of the Council.

Dated: July 7, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–14785 Filed 7–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB211]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council's is convening its Scientific and Statistical Committee (SSC) via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, July 29, 2021, beginning at 9 a.m. Webinar registration information: <https://attendee.gotowebinar.com/register/2564282533496027919>. Call in information: +1 (415) 930–5321, Access Code: 971–717–154.

ADDRESSES: Council address: New England Fishery Management Council,

50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT:

Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION: The Scientific and Statistical Committee will meet to review information presented by the Council's Skate Plan Development Team (PDT) and develop acceptable biological catch (ABC) recommendations for the Skate Complex for fishing years 2022–24. They will receive presentation on report of the SSC Social Science Subpanel Review of Groundfish and Scallops Specifications. They will discuss any comments on the document, NOAA/NMFS NS1 [National Standard 1] Technical Guidance Subgroup 3 Tech Memo. Also on the agenda is the discussion of approaches for modifying the acceptable biological catch control rules for the Northeast Multispecies (Groundfish) Fishery Management Plan. Other business will be discussed as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed 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. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

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

Dated: July 8, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-14851 Filed 7-12-21; 8:45 am]

BILLING CODE 3510-22-P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 21–1]

Thyssenkrupp Access Corp.

AGENCY: Consumer Product Safety Commission.

ACTION: Publication of a Complaint under the Consumer Product Safety Act.

SUMMARY: Under provisions of its Rules of Practice for Adjudicative Proceeding, the Consumer Product Safety Commission must publish in the **Federal Register** Complaints which it issues. Published below is a Complaint: In the matter of Thyssenkrupp Access Corp.

FOR FURTHER INFORMATION CONTACT:

Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504-7479 (Office) or 240-863-8938 (cell).

SUPPLEMENTARY INFORMATION: The Commission voted 3–1 to authorize issuance of this Complaint. Acting Chairman Adler, Commissioners Kaye and Feldman voted to authorize issuance of the Complaint. Commissioner Baiocco voted to not authorize issuance of the Complaint. The text of the Complaint appears below.

Dated: July 8, 2021.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

United States of America

Consumer Product Safety Commission

In the Matter of Thyssenkrupp Access Corp., Respondent.

CPSC Docket No.: 21–1

Complaint

Nature of the Proceedings

1. This is an administrative enforcement proceeding pursuant to Section 15 of the Consumer Product Safety Act (“CPSA”), as amended, 15 U.S.C. 2064, for public notification and remedial action to protect the public from the substantial risks of injury presented by various models of residential elevators (“Elevators”), which were manufactured and distributed by Thyssenkrupp Access Corp. (“Respondent”).

2. This proceeding is governed by the Rules of Practice for Adjudicative Proceedings before the Consumer Product Safety Commission (the “Commission”), 16 CFR part 1025.

Jurisdiction

3. This proceeding is instituted pursuant to the authority contained in Sections 15(c), (d), and (f) of the CPSA, 15 U.S.C. 2064(c), (d), and (f).

Parties

4. Complaint Counsel consists of attorneys in the Division of Enforcement and Litigation within the Office of Compliance and Field Operations representing the staff of the Commission. 16 CFR 1025.3(d). The Commission is an independent federal regulatory agency established pursuant to Section 4 of the CPSA, 15 U.S.C. 2053.

5. Respondent is a Missouri corporation with its principal place of business located at P.O. Box 545, Clinton, Missouri 64735.

6. Upon information and belief, Respondent acquired Access Industries, Inc., a manufacturer of some of the Elevators, in or about 1999.

7. Upon information and belief, Respondent acquired National Wheel-O-Vator Company, Inc., a manufacturer of some of the Elevators, in or about 2008.

8. On or about January 31, 2013, ThyssenKrupp Access Manufacturing, LLC, a manufacturer of some of the Elevators, was merged into Respondent, with Respondent being the surviving entity.

9. Upon information and belief, Respondent is a “manufacturer” and “distributor” of a “consumer product” that is “distributed in commerce,” as those terms are defined in Sections 3(a)(5), (7), (8), and (11) of the CPSA, 15 U.S.C. 2052(a)(5), (7), (8), and (11).

The Elevators

10. The Elevators are various models of residential elevators that were manufactured and/or distributed in U.S. commerce and offered for sale to consumers for their personal use in or around a permanent or temporary household or residence, school, in recreation or otherwise.

11. Upon information and belief, the Elevators include, but are not limited to, the following models: Chaparral, Destiny, LEV, LEV II, LEV II Builder, Rise, Volant, Windsor, Independence, and Flexi-Lift.

12. Upon information and belief, the Elevators were manufactured and distributed by Access Industries, Inc., formerly of Missouri; ThyssenKrupp Access Manufacturing, LLC and National Wheel-O-Vator Company, Inc., both formerly of Roanoke, Illinois; and by Respondent.

13. Upon information and belief, at least 16,872 Elevators were

manufactured and distributed in U.S. commerce from 1996 through 2012.

14. Upon information and belief, an undetermined number of Elevators were manufactured and distributed in U.S. commerce through 2012.

15. Upon information and belief, most, if not all, of the Elevators were installed by third parties based upon guidance and instructions contained in materials provided by Respondent.

16. These materials include engineering drawings and instructional materials, including installation, design, and planning guides (collectively herein, "Installation Materials.").

17. Upon information and belief, the estimated price for a two-landing installation of the Elevators was between \$15,000 to \$25,000.

18. The Elevators have a passenger car that moves between the floors in an elevator shaft, or "hoistway."

19. Access to an Elevator is restricted at each floor by a hoistway door, which often looks like a typical door installed in a consumer's residence.

20. Upon information and belief, when the Elevator is parked at a floor, the hoistway door is not locked from the exterior.

21. The Elevators also contain an interior door, the elevator car door, which is usually an accordion door or a scissor gate.

22. By design, accordion doors have v-shaped peaks and valleys that allow the door to collapse on one side of the car door and allow passengers to enter and exit the elevator.

23. This design leads to the creation of additional inches of space between the peak, which is closest to the hoistway door, and the valley, which is furthest away from the hoistway door.

24. Scissor gates are designed with metal grates and also collapse to the side of the car door to allow passengers to enter and exit the elevator.

25. Both accordion doors and scissor gates allow for deflection if pressure is exerted on the elevator car door.

26. Deflection creates additional space between the elevator car door and the hoistway door.

27. Upon information and belief, children 2-years-old and older can fit in the space between a hoistway and elevator car door if the space is greater than 4 inches.

28. The Elevators are commonly installed in homes, vacation rentals, and other premises where children are present.

The Entrapment Hazard Created by the Elevators

29. Children are likely to use an Elevator.

30. Children are likely to play in or around an Elevator.

31. Children can fit and become entrapped in the space between the hoistway door and the elevator car door when the space is greater than 4 inches ("Hazardous Space").

32. Parents or caregivers are not likely to appreciate the danger posed by a Hazardous Space between the hoistway door and elevator car door.

33. When the elevator is not operating, children can open the unlocked hoistway door, step into the Hazardous Space between the hoistway door and elevator car door, and close the hoistway door behind them.

34. Hoistway doors are designed with interlock devices, which automatically lock when the Elevator is in operation.

35. If a child is in the Hazardous Space between the hoistway and elevator car doors, and the elevator is called to another floor, the hoistway door locks, trapping the child.

36. In such a situation, a child cannot escape because the hoistway door is locked.

37. In such a situation, a parent or caregiver will likely be unable to open the hoistway door to free the child while the elevator is in operation.

38. A child entrapped in the Hazardous Space between the hoistway door and the passenger car door when an elevator is in operation can suffer serious injury or death.

39. Upon information and belief, children as young as 2 and as old as 16 have become entrapped in the Hazardous Space between the hoistway door and the elevator car door.

The Elevator Defects

40. The Elevators are defective because they contain defects in the "contents, construction, finish, packaging, warnings, and/or instructions," specifically through Respondent's Installation Materials, and the Elevators contain design defects. See 16 CFR 1115.4.

41. The Installation Materials are defective because they direct, cause, or fail to adequately prevent installation of the Elevators in a manner that creates a Hazardous Space greater than 4 inches between the hoistway door and the elevator car door.

42. The head breadths of some children can be less than 5 inches.

43. Upon information and belief, because of these dimensions, children can fit in, and become entrapped between, the hoistway and elevator car doors.

44. Certain Installation Materials are defective because they do not contain specific instructions on how to measure

the space between the hoistway door and elevator car door based on the elevator car door type (accordion or scissor).

45. Measuring to the valley versus the peak of an accordion elevator door can result in significant space variances, creating spaces much larger than 4 inches.

46. Installers using Installation Materials that do not specify how to measure are more likely to install the Elevators with a Hazardous Space because they are unlikely to appreciate the importance of minimizing the space between the hoistway door and elevator car door by measuring to the valley of the accordion door.

47. The Installation Materials that do contain specific instructions on how to measure the space do so in a manner that will create a Hazardous Space of greater than 4 inches.

48. Specifically, some of the Installation Materials affirmatively direct installers to measure the distance to the elevator car itself, the lead post of the car door, or the peak of the accordion door; all points that are inches closer to the hoistway door than the valley of the accordion door.

49. Thus, such direction makes it highly likely that installers will fail to measure to the valley of an accordion door—all but ensuring installation with a Hazardous Space of greater than 4 inches.

50. The Installation Materials also are defective because they fail to state that these measurements are safety-critical and they fail to expressly warn about the entrapment hazard posed by the Hazardous Space.

51. The Installation Materials contain many fine print measurements; failure to identify the particular measurements as a critical safety element or identify the hazard means it is less likely that there will be strict adherence to these measurements, which may lead to the creation of a Hazardous Space.

52. The Installation Materials also are defective because they do not require the use of, or provide, a measurement tool.

53. Failure to require the use of or to provide a measurement tool to ensure precise measurements between the hoistway door and the elevator car door may lead to the creation of a Hazardous Space because installers may measure in a way to create such a space.

54. This is especially problematic when installing accordion doors, because of the additional space that can be created when measuring to the peaks of the doors and not the valleys.

55. Thus, failure to require the use of or provide a measuring tool may lead to

installations where installers create a Hazardous Space by measuring to a part of the car door that would not minimize the space.

56. The Installation Materials also are defective because they fail to contain an elevator car door rigidity requirement to account for deflection of the elevator car door when minimal force is applied.

57. Deflection allows for the creation of an even larger Hazardous Space between the hoistway and elevator car doors.

58. The larger space created by deflection allows older and larger children to push against the elevator car door and become entrapped in the Hazardous Space.

59. The Elevators also are defective because they fail to provide and require use of available safety features to mitigate against the hazard.

60. Upon information and belief, Respondent sold safety features to consumers as optional items.

61. Upon information and belief, none of the Elevators come with a required safety feature that prevents a child from becoming entrapped in the Hazardous Space when the Elevator is called to another floor.

62. The design of the Elevators allows the Elevators to move from floor to floor when a child is entrapped in the Hazardous Space, putting the child at risk of serious injury or death.

63. Upon information and belief, none of the Elevators come with a required safety feature that would prevent the Elevator from moving from floor to floor if a child is entrapped in the Hazardous Space.

64. Upon information and belief, the potential for a Hazardous Space to exist between the hoistway door and elevator car door is present on all Elevator models manufactured and distributed by Respondent.

65. Upon information and belief, the potential for the Elevators to operate and move from floor to floor even if a child is entrapped in the Hazardous Space is present on all Elevator models manufactured and distributed by Respondent.

Incidents Caused by the Defective Elevators

66. The defects associated with the Elevators have led to three incidents, including the death of one child and serious and permanent injuries to another.

67. Upon information and belief, on or about December 24, 2010, a 3-year-old boy became entrapped in the Hazardous Space between the doors of a Destiny model elevator.

68. The elevator car door was an accordion door.

69. Upon information and belief, the child suffered a catastrophic brain injury when the Elevator moved between floors, and as a result, is permanently disabled.

70. The child will require constant care for the remainder of his life.

71. The Elevator was manufactured on or about September 28, 2007.

72. Upon information and belief, there were between 4.875 inches and 5 inches from the hoistway door to the peak of the accordion door, and 7.5 inches from the hoistway door to the valley of the accordion door.

73. Respondent's Installation Materials for this specific Elevator installation instructed the installer to measure 5 inches from the hoistway door to the "outside" or peak of the accordion gate.

74. Upon information and belief, on or about February 1, 2017, a 2-year-old boy died when he became entrapped in the Hazardous Space between the hoistway and accordion door of an LEV Elevator that was moving between floors.

75. Upon information and belief, the Elevator was manufactured on or about January 6, 2010.

76. Upon information and belief, on or about November 28, 2019, a 4-year-old child was entrapped in the Hazardous Space between the hoistway and accordion door of a Destiny Elevator.

77. Upon information and belief, while in the Hazardous Space, the child fell to the basement and was pinned by the Elevator.

78. This Elevator was manufactured on or about May 4, 2000.

79. Upon information and belief, the space between the hoistway door and the elevator car sill was approximately 5 inches.

80. Upon information and belief, this child was deprived of oxygen for some period of time, was hospitalized as a result of the incident, and was later released.

Respondent's Knowledge of the Defects and the Hazard

81. Upon information and belief, Respondent knew of the deadly dangers of the Hazardous Space when it manufactured and distributed the Elevators.

82. Upon information and belief, on or about July 31, 2003, National Wheel-O-Vator Company, Inc. received an "Important Elevator Safety Information Bulletin" from the Otis Elevator Company.

83. Upon information and belief, this letter and a safety brochure that

accompanied the letter, highlighted the importance of reducing the Hazardous Space by using space guards, which are safety devices that can be installed on the back of each hoistway door to eliminate some of the Hazardous Space.

84. The letter from Otis Elevator Company stated that, with space guards installed, "the likelihood of an entrapment between the door and gate and of serious injury or death is greatly reduced."

85. Upon information and belief, by 2006, members of the American Society for Mechanical Engineers A17 Residence Elevator Committee (the "Committee") publicly raised concerns regarding risks posed by the 5-inch space requirement between the hoistway door and the elevator car door found in the ASME A17.1 *Safety Code for Elevators and Escalators*.

86. Upon information and belief, various representatives for Respondent and National Wheel-O-Vator Company, Inc. participated in the Committee, including the task group manager for this issue, the vice chairman of the committee, and several other employees.

87. Upon information and belief, some Committee members noted that 5 inches between an elevator door and hoistway door could present an entrapment hazard.

88. Upon information and belief, the Committee also discussed the potential for measuring discrepancies between peaks and valleys of accordion doors.

89. Upon information and belief, the Committee also discussed the ability for accordion doors to be significantly more flexible due to deflection.

90. Upon information and belief, Respondent nevertheless made no changes to the Elevators or any Installation Materials.

91. Upon information and belief, in or about 2014, Respondent launched an information campaign, known as homeSAFE (Safety Awareness For Elevators).

92. Upon information and belief, as part of the homeSAFE campaign, Respondent offered space guards to consumers.

93. Upon information and belief, consumers were required to pay for 75% of the cost of each space guard.

94. Upon information and belief, purchasing space guards for multiple landings would cost consumers hundreds of dollars.

95. Upon information and belief, Respondent distributed approximately 422 total space guards.

96. As part of the homeSAFE campaign, on or about June 24, 2014, Respondent began recommending that

“to help prevent child entrapments, make sure the space between the hoistway door and the cab gate is no more than four inches . . . [and] taking measurements from the hoistway door to the back or rear post of the car gate.”

97. Upon information and belief, by the time that the homeSAFE campaign was launched, most, if not all, of Respondent's Elevators would have already been installed with the defective Installation Materials that allowed for a Hazardous Space greater than 4 inches and did not recommend a precise measurement to the valley of the accordion door.

98. Upon information and belief, in or about 2018, Respondent stopped supporting the homeSAFE website.

99. Despite knowing for many years about the potential hazards associated with its Elevators, Respondent took no action to correct defects in its Installation Materials or its Elevators.

100. Because of Respondent's inaction, two children were involved in incidents with Elevators manufactured after 2006; one child became permanently disabled in December 2010 and one child died in February 2017.

101. Further, two of the reported incidents occurred during or after Respondent's homeSAFE campaign; the death of a child in February 2017 and the hospitalization of a child in November 2019.

The Substantial Risk of Injury Posed by the Elevators

102. Upon information and belief, children, a vulnerable population, have sustained grievous bodily injuries and death after becoming entrapped in the Hazardous Space between the hoistway door and the elevator car door on Respondent's Elevators.

103. Upon information and belief, children are likely to interact with and playfully explore the Elevators, and it is foreseeable that children could become entrapped between the hoistway and elevator car doors.

104. Parents and caregivers are not likely to know about or appreciate the safety hazard to children posed by the Hazardous Space between the hoistway and elevator car doors.

105. Once a child enters the Hazardous Space and the elevator is called to another floor, the child cannot escape.

106. If a child is in that Hazardous Space when the elevator is called to another floor, the child is at risk of crushing injuries that can prove fatal or permanently debilitating, such as massive head trauma, compression of the torso, broken bones, and other grievous bodily injuries.

107. Children can also suffer long term complications from being crushed or dragged by an Elevator.

108. A child in the Hazardous Space when the elevator is called to another floor is also at risk of falling into the elevator shaft and suffering serious or fatal injuries.

109. Upon information and belief, at least three children have become entrapped in the Hazardous Space due to the defects associated with the Elevators.

110. The defects present in the Elevators create a substantial risk of injury to children who are entrapped in the hazardous space between the hoistway and elevator car doors when the elevator is called to another floor.

111. Death, grievous bodily injuries, and serious injuries, as defined in 16 CFR 1115.6(c) and § 1115.12(d), are likely to occur and have occurred when children become entrapped in the Hazardous Space and the Elevator is called to another floor.

Legal Authority Under the CPSA

112. Under the CPSA, the Commission may order a firm to provide notice to the public and take remedial action if the Commission determines that a product “presents a substantial product hazard.” 15 U.S.C. 2064(c) and (d).

113. Under CPSA Section 15(a)(2), a “substantial product hazard” is “a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.” 15 U.S.C. 2064(a)(2).

114. A product may contain a design defect even if it is manufactured exactly in accordance with its design and specifications if the design presents a risk of injury to the public. 16 CFR 1115.4.

115. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions.

116. A consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury. 16 CFR 1115.4.

Count I

The Elevators Are a Substantial Product Hazard Because They Contain Defects That Create a Substantial Risk of Injury to the Public

117. Paragraphs 1 through 116 are hereby realleged and incorporated by reference as if fully set forth herein.

118. The Elevators are consumer products.

119. The Elevators contain defects because:

a. The Installation Materials direct, cause, or fail to adequately prevent installation of the Elevators in a manner that creates a Hazardous Space between the hoistway door and elevator car doors in which children can become entrapped, including by failing to:

i. Contain adequate and correct instructions on how to measure the space between the hoistway door and elevator car door to avoid creating the Hazardous Space based on the elevator car door type;

ii. contain adequate instructions on how to avoid the creation of a larger Hazardous Space based on the deflection of the elevator car door;

iii. state that the measurement between the hoistway door and the elevator car door is safety-critical or expressly warn about the entrapment hazard; and

iv. require the use of, or provide, a measurement tool to ensure precise measurement and avoid the creation of a Hazardous Space.

b. The design of the Elevators fails to require safety features that prevent a child from becoming entrapped in the Hazardous Space and that prevent the Elevator from moving between floors if a child is entrapped in the Hazardous Space.

120. These defects separately, and in combination, create a substantial risk of injury to the public because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise.

121. Therefore, the Elevators present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA, 15 U.S.C. 2064(a)(2).

Relief Sought

Wherefore, in the public interest, Complaint Counsel requests that the Commission:

A. Determine that the Elevators present a “substantial product hazard” within the meaning of Section 15(a)(2) of the CPSA, 15 U.S.C. 2064(a)(2).

B. Determine that extensive and effective public notification under Section 15(c) of the CPSA, 15 U.S.C. 2064(c), is required to adequately protect the public from the substantial product hazard presented by the Elevators, and order Respondent under Section 15(c) of the CPSA, 15 U.S.C. 2064(c), to:

(1) Notify all persons who distribute the Elevators, or to whom such Elevators have been sold or distributed,

to immediately cease distribution of the Elevators;

(2) Notify appropriate state and local public health officials;

(3) Give prompt public notice of the defect in the Elevators, including the incidents and injuries associated with the use of the Elevators, including posting clear and conspicuous notice on Respondent's website, and providing notice to any third-party website on which Respondent has a presence, and provide further announcements in languages other than English and on radio, television, and social media;

(4) Mail and email notice to each distributor, retailer, dealer and installer of the Elevators; and

(5) Mail and email notice to every person to whom the Elevators were delivered or sold.

C. Determine that action under Section 15(d) of the CPSA, 15 U.S.C. 2064(d), is in the public interest and additionally order Respondent to:

(1) Repair the defect in the Elevators by providing a free inspection to consumers by a qualified inspector who will measure the gap between the hoistway and elevator doors;

(2) Install, at no cost to consumers, a free space guard approved by Commission staff that reduces the gap to no more than 4 inches;

(3) Make no charge to consumers, and to reimburse consumers, for any reasonable and foreseeable expenses incurred in availing themselves of any remedy provided under any Commission Order issued in this matter, as provided by Section 15(e)(1) of the CPSA, 15 U.S.C. 2064(e)(1), including previous purchases of space guards or other safety devices, and all costs associated with those purchases, whether or not they were part of the homeSAFE campaign;

(4) Reimburse distributors, retailers, dealers, installers, and other third parties for expenses in connection with carrying out any Commission Order issued in this matter, including the costs of repairs or replacements, as provided by Section 15(e)(2) of the CPSA, 15 U.S.C. 2064(e)(2);

(5) Submit a plan satisfactory to the Commission, within ten (10) days of service of the Final Order, directing that actions specified in Paragraphs B(1) through (5), and C(1) through (4) above be taken in a timely manner;

(6) Submit monthly reports, to the Commission, documenting the progress of the corrective action program;

(7) For a period of five (5) years after issuance of the Final Order in this matter, keep records of its actions taken to comply with Paragraphs B(1) through (5), C(1) through (4), above, and supply

these records to the Commission for the purpose of monitoring compliance with the Final Order; and

(9) For a period of five (5) years after issuance of the Final Order in this matter, notify the Commission at least sixty (60) days prior to any change in its business (such as incorporation, dissolution, assignment, sale, or petition for bankruptcy) that results in, or is intended to result in, the emergence of a successor corporation, going out of business, or any other change that might affect compliance obligations under a Final Order issued by the Commission in this matter.

D. Order that Respondent take other and further actions as the Commission deems necessary to protect the public health and safety and to comply with the CPSA.

Issued by Order of the Commission:
Dated this 7th day of July, 2021

By: Robert Kaye,
Assistant Executive Director, Office of Compliance and Field Operations, (301) 504-6960.

Mary B. Murphy,
Director, Division of Enforcement and Litigation.

Gregory M. Reyes,
Trial Attorney.

Michael J. Rogal,
Trial Attorney.

Complaint Counsel, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, Bethesda, MD 20814, Tel: (301) 504-7809.

United States of America Consumer Product Safety Commission

In the Matter of Thyssenkrupp Access Corp., Respondent.

CPSC DOCKET NO.: 21-1

List and Summary of Documentary Evidence

Pursuant to 16 CFR 1025.11(b)(3) of the Commission's Rules of Practice for Adjudicative Proceedings, the following is a list and summary of documentary evidence supporting the charges in this matter. Complaint Counsel reserves the right to offer additional or different evidence during the course of the proceedings, or to withhold evidence on the basis of any applicable legal privileges.

1. Claims, complaints, records, reports, CPSC's In-Depth Investigations, and lawsuits concerning incidents or injuries involving various models of residential elevators manufactured and distributed by Respondent ("Elevators").

2. Engineering drawings and instructional materials, including installation, design, and planning

guides (referred to as "Installation Materials").

3. Design, manufacturing, distribution, warnings, instructions, and promotional materials associated with the Elevators.

4. CPSC Product Safety Assessments.

5. Correspondence between Respondent and CPSC staff related to the Elevators.

6. Documents and information related to the Elevators, including notices issued regarding the Elevators and similar products.

7. Documents and information related to Respondent's corporate structure and Respondent's acquisition of and merger with other manufacturers and distributors of the Elevators.

Dated this 7th day of July, 2021

Mary B. Murphy,
Director.

Gregory M. Reyes,
Trial Attorney.

Michael J. Rogal,
Trial Attorney.

Division of Enforcement and Litigation, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, Bethesda, MD 20814, Tel: (301) 504-7809.

Complaint Counsel for U.S. Consumer Product Safety Commission.

Certificate of Service

I hereby certify that on July 7, 2021, I served the foregoing Complaint and List and Summary of Documentary Evidence upon all parties of record in these proceedings by emailing a copy to counsel, as follows:

Sheila A. Millar,
Steven Michael Gentine,

Keller and Keckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001.

Email: millar@khlaw.com, gentine@khlaw.com.

Gregory M. Reyes,

Complaint Counsel for U.S. Consumer Product Safety Commission.

[FR Doc. 2021-14819 Filed 7-12-21; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Extension of Public Comment Period for the Draft Environmental Impact Statement for the Navy Old Town Campus Revitalization

AGENCY: Department of the Navy, DoD.

ACTION: Notice of extension.

SUMMARY: A notice of availability was published in the **Federal Register** by the U.S. Environmental Protection Agency

on May 14, 2021 for the Department of the Navy's (DoN) Draft Environmental Impact Statement for the Navy Old Town Campus (OTC) Revitalization. This notice announces a 30-day extension of the public comment period from July 13, 2021 to August 12, 2021.

DATES: The public comment period began on May 14, 2021 and will end on August 12, 2021. To be considered in the Final EIS, all comments must be postmarked or received online by 11:59 p.m. Pacific Standard Time on August 12, 2021.

ADDRESSES: Written comments may be submitted electronically on the project website at www.NAVWAR-revitalization.com or by mail to: Navy OTC Revitalization EIS Project Manager, Attention: Ron Bochenek, 750 Pacific Highway, Floor 12, San Diego, CA 92132-0058.

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Systems Command Southwest, Attention: Ron Bochenek, Navy OTC Revitalization EIS Project Manager, 750 Pacific Highway, Floor 12, San Diego, CA 92132-0058, 888-682-6289, info@NAVWAR-revitalization.com. You can also visit the project website at www.NAVWAR-revitalization.com for more information.

SUPPLEMENTARY INFORMATION: The Draft EIS and informational materials are available on the project website at www.NAVWAR-revitalization.com. The public may also review the Draft EIS and select materials at the following libraries:

1. Mission Hills-Hillcrest/Knox Library (215 West Washington Street, San Diego, CA 92103)
2. Point Loma/Hervey Library (3701 Voltaire Street, San Diego, CA 92107)
3. San Diego Central Library (330 Park Boulevard, San Diego, CA 92101)

Dated: July 8, 2021.

K.R. Callan,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2021-14841 Filed 7-12-21; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF EDUCATION

Applications for New Awards; American Rescue Plan—American Indian Resilience in Education (ARP— AIRE)

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting

applications (NIA) for fiscal year (FY) 2021 for the American Rescue Plan—American Indian Resilience in Education (ARP—AIRE) program, Assistance Listing Number 84.299C. This notice relates to the approved information collection under OMB control number 1894-0006.

DATES:

Applications Available: July 13, 2021.

Deadline for Notice of Intent to Apply: July 23, 2021.

Date of Pre-Application Webinar: July 28, 2021.

Individuals interested in attending this webinar for prospective applicants are encouraged to pre-register by emailing their name, organization, and contact information with the subject heading "ARP—AIRE GRANTS PRE-APPLICATION WEBINAR" to shahla.ortega@ed.gov. There is no registration fee to attend this meeting. Information regarding pre-application webinar is available by accessing the website: <https://oese.ed.gov/offices/office-of-indian-education/>.

Deadline for Transmittal of Applications: September 13, 2021.

Deadline for Intergovernmental Review: October 12, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.

FOR FURTHER INFORMATION CONTACT:

Shahla Ortega, U.S. Department of Education, 400 Maryland Avenue SW, Room 3W245, Washington, DC 20202. Telephone: (202) 453-5602. Email: shahla.ortega@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the ARP—AIRE program is to support Tribal educational agencies (TEAs) in the provision of direct services to Indian children and youth. Projects must include one or more of the activities authorized under section 6121(c) of the Elementary and Secondary Education Act of 1965, as amended (ESEA).

Background: ARP—AIRE is a one-time discretionary grant competition

authorized under Section 11006(1) of the American Rescue Plan Act of 2021 (ARP) to provide awards to TEAs for activities authorized under section 6121(c) of the ESEA in order to meet the urgent needs of students in response to the Coronavirus 2019 (COVID-19) pandemic. Those activities include a broad range of direct services to Indian children and youth, their teachers, and families.

In accordance with the Department's commitment to engage in regular and meaningful consultation and collaboration with Indian Tribes, the Office of Elementary and Secondary Education's (OESE) Office of Indian Education (OIE) and the White House Initiative on American Indian and Alaska Native Education (WHIAIANE) conducted a virtual Tribal consultation session regarding the ARP—AIRE program on April 26, 2021. Consistent with the Department's trust responsibility to Tribes and its Tribal consultation Policy, the Department consulted with elected officials of federally recognized Tribes to ensure that their views inform the Department's policy decisions related to the priorities, requirements, and definitions that govern this competition. In addition to the virtual Tribal consultation, Tribal leaders and others had an opportunity to submit written comments to the Department by email. We solicited feedback on specific questions related to the design of this grant program during this Tribal consultation opportunity. A summary of the feedback to these questions and how we incorporated the feedback into this NIA follows.

1. We asked whether we should adopt the definition of TEA used in the State Tribal Education Partnership (STEP) program for the ARP—AIRE program, which is: "the agency, department, or instrumentality of an Indian Tribe that is primarily responsible for supporting Tribal students' elementary and secondary education." A significant number of comments from both Tribal leaders and others expressed interest in using the same definition from the STEP program. A commenter expressed interest in adding postsecondary education, and another proposed adding online students, to the definition. Because the activities in ESEA section 6121(c) are focused on pre-kindergarten (Pre-K) to grade 12 education, we are limiting the scope of this program to students in those grade levels. This scope covers students in a TEA's geographic area, regardless of whether students attend school in person or online. Thus, we are using the STEP definition of TEA in this ARP—AIRE program competition.

2. We asked whether there were other considerations for how “TEA” should be defined for this new grant program. Some commenters expressed interest in adding Pre-K and early childhood to the definition of TEA. Although we are not expanding the definition of TEA, the activities in ESEA section 6121(c) do include early childhood education, and accordingly we are including language in the absolute priority to provide applicants an opportunity to select project activities that would address any grade level from Pre-K through grade 12.

3. We asked how long the grant period should be for the ARP–AIRE program and provided examples of 3-year, 4-year, and 5-year grant periods. A majority of Tribal leaders and other commenters suggested that the program performance period be a 5-year period. We considered this input, but weighed it against the fact that, given the one-time nature of these ARP funds, we could award more 3-year awards than 5-year awards, and the fact that the ARP funding is emergency funding from Congress to address immediate needs caused by the pandemic. We also believe that a grant period shorter than three years would not give grantees adequate time to successfully implement projects. We have decided to use a 3-year grant period in order to maximize the number of awards available and reach the maximum number of Tribal communities throughout the country to support effective responses to the pandemic.

4. We explained that we were considering prioritizing certain project activities from the full list of allowable activities in ESEA section 6121(c). All of the allowable activities are for direct services to Indian children and youth in Pre-K through twelfth grade, and/or their teachers and parents. We asked Tribal representatives to select two of the listed activities that most interest their Tribal Nation. The most popular activities selected by participants were Native language programs; services to assist and encourage students to enter, remain in, or reenter school; and incorporation of culturally relevant pedagogy into local school curricula. However, the majority of comments from Tribal leaders and others strongly recommended that TEAs be able to choose their grant focus from among the activities listed in section 6121(c) of the ESEA. We agree with Tribal leaders and other commenters that allowing applicants to choose their activities better supports Tribal sovereignty.

The Department has designed one absolute priority that we believe meets these various goals; the absolute priority requires culturally relevant projects

designed to assist and encourage Indian children and youth to enter, remain in, or reenter school at any grade level from Pre-K through grade 12, that include at least one of the activities from section 6121(c) of the ESEA. We omitted section 6121(c)(5) because it is incorporated into the introductory language of the absolute priority, and section 6121(c)(14) because it is only relevant to the Demonstration Grants program. Under this absolute priority, applicants can choose one or more of the activities, such as native language instruction, remedial instruction, or Pre-K education, and must show how it is culturally relevant and how it is designed to help students enter, remain in, or reenter school.

We included in the introductory language of the absolute priority the focus on activities that assist and encourage Indian children and youth to enter, remain in, or reenter school, because two decades of research literature shows that there is a clear need to identify strategies to help keep Indian children and youth in school (Withington A., & Shtivelband, A., 2014).¹ We included the requirement that all projects use culturally related activities because research has shown that such activities improve the academic achievement of American Indian/Alaska Native students (McCarty, 2011;² Faircloth & Tippeconic, 2000;³ Kim & Helphenstine, 2017; Thomas & Collier, 1997⁴).

5. We asked whether we should prioritize novice applicants by including a competitive preference priority that awards additional points to applicants that have not received a grant from the Department within a certain time period. The majority of comments were in favor of the Department including a competitive preference priority to encourage novice applicants to give an advantage to TEAs that have

not previously been awarded grants from the Department. We agree and have included a competitive preference priority for novice applicants in the competition. For this competition, a “novice” applicant is one that has not had an active discretionary grant from the Department in the past five years. If an applicant received a grant during that period only as a member of a consortium in which it was not the lead applicant, the applicant will still receive the novice priority points. For an applicant that is a consortium of TEAs, if the lead applicant has not had an active discretionary grant from the Department in the past five years, it will receive the novice points even if not all consortium members meet the novice requirement.

6. We asked how we should measure the success of these projects and included the following measures as examples: The number and percentage of participating students who demonstrate an increase in attendance rate; increase in graduation rate; improved academic performance; and improved social, emotional and mental health. As a related matter, we asked whether we should require grantees to track student-level data and, specifically, graduation rates. The majority of comments suggested the Department measure the success of project performance using attendance, academic performance, and other means as defined by the TEA. While we generally agree that each of these are important, because we anticipate that projects will focus on many types of activities, the Department will measure success by determining the number of grantees that attain or exceed the targets for the outcome indicators that have been approved by the Secretary for their projects.

As part of these questions, we also asked whether we should require grantees to track these measures during a data collection period after the substantive project activities have ended. A majority of the comments from Tribal leaders and others suggested that grantees should track measures beyond the performance period. While we generally agree, we also had many requests during consultation to keep the program design simple and minimize program requirements. Therefore, we will not incorporate a program requirement relating to long-term data collection; however, we may consider grant extensions for data collection in the future.

7. We asked whether we should require grantees to enter into written data-sharing agreements with the school districts attended by students

¹ Withington A., & Shtivelband, A. (2014). Native American student-dropout prevention strategies: Abstracts from the literature. (A report from the West Comprehensive Center.) San Francisco, CA: WestEd.

² McCarty, T. (2011). The role of Native languages and cultures in American Indian, Alaska Native, and Native Hawaiian student achievement. A revised version of a policy brief prepared for the Promising Practices and Partnerships in Indian Education (P3IE) Program Evaluation Group, under a contract from the U.S. Department of Education Office of Indian Education Programs in 2009.

³ Faircloth, S., & Tippeconic, J.W., III. (2000). Issues in the education of American Indian and Alaska Native students with disabilities. ERIC Number: ED448009.

⁴ Thomas, W.P., & Collier, V. (1997). School effectiveness for language minority students. The George Washington University, Washington, DC: National Clearing House for Bilingual Education. ERIC Number: ED436087.

participating in their projects. The purpose of such agreements would be to ensure that grantees have the data needed to report on measures we might require of all grantees, as well as their own project-specific objectives. Results were mixed from Tribal leaders as to whether the Department should impose an application requirement for a data-sharing agreement with partner schools. Most other commenters suggested that TEAs should be required to enter a data-sharing agreement with partner schools prior to applying. One commenter suggested that data-sharing agreements could be entered into at any appropriate point in the grant process and do not necessarily need to be entered into prior to submitting a grant application. While we generally agree that data-sharing agreements are conducive to effective project performance, we do not want to impose an application requirement that we understand can be very time-consuming and that might lead to TEAs being unable to meet the application deadline. Instead, we have created a program requirement for a data-sharing agreement to allow grantees the flexibility to obtain those agreements during the first six months of their performance period.

8. We asked Tribal leaders and other participants to comment on any other application or program requirements that we should consider. Commenters suggested that we require family engagement and minimize reporting burden on grantees as much as possible. We recognize the importance of promoting family engagement and reducing reporting burden and have taken those into consideration. While we agree that family engagement is important, we also want to simplify the application and be respectful of Tribal sovereignty, so we are not adding an additional program requirement around family engagement. With regard to reporting burdens, there are Department-wide requirements around annual reporting in the Annual Performance Report (APR), and we believe that APR reporting serves a valuable function in ensuring ongoing progress and enabling us to provide assistance to grantees who may be struggling to achieve adequate progress.

Priorities: This notice contains one absolute priority and one competitive preference priority. We are establishing these priorities for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priority: This priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

American Indian Resilience in Education.

To meet this priority, applicants must propose a culturally relevant project designed to assist and encourage Indian children and youth to enter, remain in, or reenter school at any grade level from Pre-K through grade 12, that includes at least one of the following activities from section 6121(c) of the ESEA:

(1) Innovative programs related to the educational needs of educationally disadvantaged Indian children and youth.

(2) Educational services that are not available to such children and youth in sufficient quantity or quality, including remedial instruction, to raise the achievement of Indian children in one or more of the subjects of English, mathematics, science, foreign languages, art, history, and geography.

(3) Bilingual and bicultural programs and projects.

(4) Special health and nutrition services, and other related activities, that address the special health, social, and psychological problems of Indian children and youth.

(5) Comprehensive guidance, counseling, and testing services.

(6) Early childhood education programs that are effective in preparing young children to make sufficient academic growth by the end of grade 3, including kindergarten and Pre-K programs, family-based preschool programs that emphasize school readiness, screening and referral, and the provision of services to Indian children and youth with disabilities.

(7) Partnership projects between local educational agencies and institutions of higher education that allow secondary school students to enroll in courses at the postsecondary level to aid such students in the transition from secondary to postsecondary education.

(8) Partnership projects between schools and local businesses for career preparation programs designed to provide Indian youth with the knowledge and skills such youth need to make an effective transition from school to a high-skill career.

(9) Programs designed to encourage and assist Indian students to work toward, and gain entrance into, institutions of higher education.

(10) Family literacy services.

(11) Activities that recognize and support the unique cultural and educational needs of Indian children

and youth, and incorporate traditional leaders.

(12) High-quality professional development of teaching professionals and paraprofessionals.

Competitive Preference Priority: This priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award an additional five points to an application that meets this priority.

This priority is:

Applicants that are New Potential Grantees. (0 or 5 points)

To meet this priority, the applicant has not had an active discretionary grant from the Department in the past five years. For an applicant that is a consortium of TEAs, if the lead applicant meets this requirement, it will receive the novice points even if not all consortium members meet this requirement.

Requirement: We are establishing this program requirement for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA.

Program Requirement: Within six months after the date of the award, the grantee must submit to the Department a signed, written agreement with each LEA where participating students are enrolled. The agreement must include provisions that allow the grantee to access data necessary for the success of the project and for reporting on project objectives. Agreements between Tribally-controlled schools and grantees are not required if the school and grantee are controlled by the same Tribe.

Statutory Hiring Preference:

(a) Awards that are primarily for the benefit of Indians are subject to the provisions of section 7(b) of the Indian Self-Determination and Education Assistance Act (Pub. L. 93-638). That section requires that, to the greatest extent feasible, a grantee—

(1) Give to Indians preferences and opportunities for training and employment in connection with the administration of the grant; and

(2) Give to Indian organizations and to Indian-owned economic enterprises, as defined in section 3 of the Indian Financing Act of 1974 (25 U.S.C. 1452(e)), preference in the award of contracts in connection with the administration of the grant.

(b) For purposes of this preference, an Indian is a member of any federally recognized Indian Tribe.

Definitions: The following definitions apply to this competition. We are establishing the definitions of “Indian” and “Tribal Educational Agency” in this

notice for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA. The definitions of “demonstrates a rationale” and “logic model” are from 34 CFR 77.1.

Demonstrates a Rationale means a key project component included in the project’s logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Indian means an individual who is—

(1) A member of an Indian Tribe or band, as membership is defined by the Indian Tribe or band, including any Tribe or band terminated since 1940, and any Tribe or band recognized by the State in which the Tribe or band resides;

(2) A descendant of a parent or grandparent who meets the requirements described in paragraph (1) of this definition;

(3) Considered by the Secretary of the Interior to be an Indian for any purpose;

(4) An Eskimo, Aleut, or other Alaska Native; or

(5) A member of an organized Indian group that received a grant under the Indian Education Act of 1988 as it was in effect on October 19, 1994.

Logic Model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.*, the active “ingredients” that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Tribal Educational Agency (TEA) means the agency, department, or instrumentality of one or more federally-recognized or State-recognized Indian Tribes, that is primarily responsible for supporting Tribal students’ elementary and secondary education.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, requirements, and definitions. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 11006(1) of the ARP (Pub. L. 117–2), and, therefore, qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities,

requirements, and definitions under section 437(d)(1) of GEPA. These priorities, requirements, and definitions will apply to the FY 2021 competition, and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: Section 11006 of the American Rescue Plan Act of 2021 (ARP), Public Law 117–2.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds:

\$19,800,000 for three years.

Estimated Range of Awards: \$300,000 to \$500,000 for each 12-month budget period.

Estimated Average Size of Awards: \$400,000 for each 12-month budget period.

Estimated Number of Awards: 16 for each 12-month budget period.

Note: The Department is not bound by any estimates in this notice.

Project Period: 36 months.

III. Eligibility Information

1. *Eligible Applicants:* TEAs, including a consortium of TEAs.

Note: If applying as a consortium, applicants should refer to 34 CFR 75.127–75.129 for information about group applications.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see www2.ed.gov/about/offices/list/ocfo/intro.html.

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform

to the Cost Principles in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. Application Submission

Instructions: Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf, which contain requirements and information on how to submit an application.

2. Submission of Proprietary

Information: Given the types of projects that may be proposed in applications for the ARP–AIRE program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define “business information” and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended). Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under “Other Attachments Form,” please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program. Please note that, under 34 CFR 79.8(a), we have shortened the standard 60-day intergovernmental review period in order to make awards by the end of FY 2021.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your

application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A “page” is 8.5” x 11”, on one side only, with 1” margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line “Intent to Apply,” and include the applicant’s name and a contact person’s name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210. We will award up to 100 points to an application under the selection criteria; the total possible points for each selection criterion are noted in parentheses.

(a) *Quality of the project design (up to 50 points).*

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the design of the proposed project includes a thorough, high-quality review of the relevant literature, a high-quality plan for project implementation, and the use of appropriate methodological tools to ensure successful achievement of project objectives. (20 points)

(ii) The extent to which the proposed project encourages parental involvement. (10 points)

(iii) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (10 points)

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible. (10 points)

(b) *Quality of project services (up to 20 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (1 point)

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services. (4 points)

(ii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice. (10 points)

(iii) The likely impact of the services to be provided by the proposed project on the intended recipients of those services. (5 points)

(c) *Quality of project personnel (up to 15 points).*

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are

members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (3 points)

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator. (7 points)

(ii) The qualifications, including relevant training and experience, of key project personnel. (5 points)

(d) *Quality of the management plan (up to 15 points).*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (10 points)

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (5 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant’s use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of

unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer

effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report

that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of the Government Performance and Results Act of 1993 and for Department reporting under 34 CFR 75.110, we have established the following performance measure for the ARP–AIRE program:

The number of grantees that attain or exceed the targets for the outcome indicators that have been approved by the Secretary for their projects.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021-14858 Filed 7-12-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Applications for New Awards; National Comprehensive Center on Improving Literacy for Students With Disabilities

AGENCY: Offices of Elementary and Secondary Education and Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for a new award for fiscal year (FY) 2021 for a National Comprehensive Center on Improving Literacy for Students with Disabilities (Comprehensive Centers program), Assistance Listing Number 84.283D. This notice relates to the approved information collection under OMB control number 1894-0006.

DATES:

Applications available: July 13, 2021.
Deadline for transmittal of applications: September 1, 2021.

Pre-Application Webinar Information: No later than July 19, 2021, the Office of Special Education Programs (OSEP) will post a pre-recorded informational webinar designed to provide technical assistance (TA) to interested applicants.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at

www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.

The webinar may be found at www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.

FOR FURTHER INFORMATION CONTACT: Tina Diamond, U.S. Department of Education, 400 Maryland Avenue SW, Room 5142, Potomac Center Plaza, Washington, DC 20202-5076. Telephone: (202) 245-6723. Email: Christina.Diamond@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the National Comprehensive Center on Improving Literacy for Students with Disabilities (Center) is to identify or develop evidence-based literacy assessment tools and professional development activities and identify evidence-based instruction, strategies, and accommodations for students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. The Center will also disseminate its products and information on evidence-based literacy to families, SEAs, LEAs, REAs, and schools.

Priority: This priority is from the notice of final priority, requirement, and definitions (NFP) for this program published elsewhere in this issue of the **Federal Register**.

Absolute Priority: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

National Comprehensive Center on Improving Literacy for Students with Disabilities.

Background:

Section 2244 of the Elementary and Secondary Education Act, as amended (ESEA) requires the Secretary to establish a comprehensive center on students at risk of not attaining full literacy skills due to a disability. Comprehensive centers are typically administered by the Office of Elementary and Secondary Education (OESE). OESE is funding this Center;

however, because of the Center's subject matter, it will be administered jointly by OESE and OSEP in the Office of Special Education and Rehabilitative Services (OSERS).

The project is designed to improve implementation of evidence-based literacy practices in both teacher classroom and remote learning environments. With respect to remote learning, the priority is intended to ensure that teachers have the training and support they need to implement evidence-based literacy practices during remote instruction for students with disabilities, including students with dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. Remote learning plays a critical role in regular instruction and can serve as a crucial link allowing high-quality teaching and learning to continue when regular instruction is disrupted.

Priority:

The purpose of this priority is to fund a cooperative agreement to establish and operate a National Comprehensive Center on Improving Literacy for Students with Disabilities (Center) for children in early childhood education programs through high school. The Center must—

(a) Identify or develop free or low-cost evidence-based assessment tools for identifying students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning;

(b) Identify evidence-based literacy instruction, strategies, and accommodations, including assistive technology, designed to meet the specific needs of such students;

(c) Provide families of such students with information to assist such students;

(d) Identify or develop evidence-based professional development for teachers, paraprofessionals, principals, other school leaders, and specialized instructional support personnel to—

(1) Understand early indicators of students at risk of not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning;

(2) Use evidence-based screening assessments for early identification of

such students beginning not later than kindergarten;¹ and

(3) Implement evidence-based instruction designed to meet the specific needs of such students; and

(e) Disseminate the products of the comprehensive center to regionally diverse SEAs, REAs, LEAs, and schools, including, as appropriate, through partnerships with other comprehensive centers established under section 203 of the Educational Technical Assistance Act of 2002 (20 U.S.C. 9602), and regional educational laboratories established under section 174 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9564).

In addition to these programmatic requirements, to be considered for funding under this priority, applicants must meet the application and administrative requirements in this priority, which are:

(a) Demonstrate, in the narrative section of the application under “Significance,” how the proposed project will—

(1) Address current and emerging training and information needs of SEAs, REAs, LEAs, TA centers, schools, and practitioners to select and implement teacher classroom and remote learning environment evidence-based practices (EBPs) that will improve literacy outcomes for students with disabilities, including students with dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. To meet this requirement, the applicant must—

(i) Demonstrate knowledge of current and emerging EBPs, which can be used in reading and literacy-related teacher classroom and remote learning environment instruction, screening, assessment, and identification or diagnosis of students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. This includes demonstrating knowledge of current and emerging reading and literacy-related EBPs for students who are English learners; students from a variety of settings (e.g., rural, suburban, urban); students from low-income families; and other educationally disadvantaged students; or

(ii) Demonstrate knowledge of, previous experience with, and results of using creative approaches and implementing in-person and virtual TA strategies to provide capacity-building services and disseminate teacher classroom and remote learning environment EBPs to a variety of entities, including parents, SEAs, REAs, LEAs, schools, Head Start, and other early childhood programs;

(2) Demonstrate a record of improving outcomes in literacy achievement for students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning, in order to better prepare them to compete in a global economy; and

(3) Demonstrate a record of improving the adoption, implementation, and sustainment of teacher classroom and remote learning environment EBPs in literacy instruction for students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning.

(b) Demonstrate, in the narrative section of the application under “Quality of project services,” how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, sex, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that products and services meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended short-term, intermediate, and long-term outcomes. To meet this requirement, the applicant must provide—

(i) A five-year plan for the Center to identify current and emerging training and information needs and to address the priority;

(ii) Measurable intended project outcomes; and

(iii) In Appendix A, the logic model (as defined in 34 CFR 77.1) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended short-term, intermediate, and long-term outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, and describe any underlying concepts, assumptions, expectations, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks:

www.osepideasthatwork.org/logicModel,
www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework, and
www.federalregister.gov/d/2019-06583.

(4) Be based on current research and make use of EBPs in the development and delivery of its products and services. To meet this requirement, the applicant must describe—

(i) The current research on teacher classroom and remote learning environment EBPs for literacy instruction for students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning;

(ii) The current research on teacher classroom and remote learning environment EBPs for assessing students at risk for not attaining full literacy skills due to a disability, including dyslexia impacting reading or writing, or developmental delay impacting reading, writing, language processing, comprehension, or executive functioning. This should include the current research on screening assessments for dyslexia and other literacy-related disabilities that are evidence-based, psychometrically valid, free or low-cost, efficient to scale, and readily available for use; and

(iii) The current research about adult learning principles in in-person and virtual settings and implementation science that will inform the proposed TA; and

(5) Develop products or refine or update publicly available existing products and provide in-person and virtual services that are of high quality and sufficient intensity and duration to achieve the intended measurable outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify or develop the knowledge base in teacher classroom and remote learning environment literacy instruction for students at risk of not attaining full literacy skills due to a disability;

¹ Applicants are encouraged to identify or develop professional development for using evidence-based screening assessments for early identification of children in early childhood or prekindergarten programs, as well.

(ii) Its proposed approach to universal, general TA, which must identify the intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(iii) Its proposed approach to targeted, specialized TA, which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services under this approach, a description of new or existing publicly available products that may be used and services that the Center proposes to make available, and the expected impact of those products and services under this approach; and

(B) Its proposed approach to measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the local level; and

(iv) Its proposed approach to intensive, sustained TA, which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services, a description of new or existing publicly available products that may be used and services that the Center proposes to make available, and the expected impact of those products and services under this approach;

(B) Its proposed approach to measure the readiness of the target audiences to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability to build capacity at the SEA, REA, LEA, school, and early childhood education program levels;

(C) Its proposed plan for assisting SEAs, REAs, and LEAs to build or enhance in-person and virtual training systems that include capacity-building services and professional development based on adult learning principles and coaching; and

(D) Its proposed plan for working with appropriate levels of the education system (e.g., SEAs, regional TA providers, districts, schools, early childhood education programs, families) to ensure that there is communication between each level and that there are systems in place to support the use of teacher classroom and remote learning environment EBPs for literacy instruction;

(6) Partner with the National Comprehensive Center and at least one of the other federally funded comprehensive centers, regional educational laboratories, equity assistance centers, OSEP- and other

related federally funded TA Centers, parent training and information and community parent resource centers funded by the Department and OSEP (e.g., Center for Parent Information and Resources and Parent Technical Assistance Centers), and other related organizations to refine or develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes; and

(7) Develop a dissemination plan that describes how the applicant will systematically distribute information, products, and services to varied intended audiences, using a variety of in-person and virtual dissemination strategies, to promote awareness and use of the Center's products and services.

(c) In the narrative section of the application under "Quality of the project evaluation," include an evaluation plan for the project developed in consultation with and implemented by a third-party evaluator. The evaluation plan must—

(1) Articulate formative and summative evaluation questions, including important process and outcome evaluation questions, that are linked directly to the project's proposed logic model required in paragraph (b)(2)(iii) of this notice;

(2) Describe how progress in and fidelity of implementation, as well as project short-term, intermediate, and long-term outcomes, will be measured to answer the evaluation questions. Specify the measures and associated instruments or sources for data appropriate to the evaluation questions. Include information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and improve service delivery over the course of the project and to refine the proposed logic model and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation and include staff assignments for completing the plan. The timeline must indicate that the data will be available annually for the annual performance report (APR); and

(5) Dedicate sufficient funds in each budget year to cover the costs of

developing or refining the evaluation plan in collaboration with a third-party evaluator and the costs associated with the implementation of the evaluation plan by the third-party evaluator.

(d) Demonstrate, in the narrative section of the application under "Adequacy of resources and quality of project personnel," how—

(1) The proposed project will ensure equal access for employment for all, including those who are members of groups that have traditionally been underrepresented based on race, color, national origin, sex, age, religion, or disability;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications, subject-matter expertise, and technical experience to carry out the proposed activities, achieve the project's intended outcomes, and develop ongoing partnerships with leading experts and organizations nationwide to inform project activities;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under "Quality of the management plan," how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes. The identified project director should be, at minimum, 0.5 full-time equivalency throughout the project period;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, general and special education teachers, paraprofessionals, principals, other school leaders, specialized instructional support personnel, TA providers, researchers, institutions of higher education (IHEs), and policy makers,

among others, in its development and operation.

(f) Address the following additional application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, or virtually, after receipt of the award, and an annual planning meeting in Washington, DC, or virtually, with the OSEP project officer, OESE staff, and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative;

(ii) A two and one-half day project directors' conference in Washington, DC, or a virtual conference, during each year of the project period;

(iii) Two annual two-day trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP; and

(iv) At least monthly, communicate and collaborate with other Department-funded centers to achieve project objectives;

(3) Include, in the budget, a line item for an annual set-aside of 5 percent of the grant amount to support emerging needs that are consistent with the proposed project's intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(4) Include a plan for maintaining a high-quality website, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility;

(5) Include a plan for ensuring that annual project progress toward meeting project goals is posted on the project website;

(6) Include, in Appendix A, a letter of agreement from each partnering organization or consultant. The letter of agreement should clearly specify the role of the partnering organization or consultant and the time needed to fulfill the commitment to the project; and

(7) Include, in Appendix A, an assurance to assist OSEP and OESE with

the transfer of pertinent resources and products and to maintain the continuity of services to target audiences during the transition to this new award period and at the end of this award period, as appropriate.

Definitions:

The following definitions apply to this competition. We provide the source of the definitions in parentheses.

Capacity-building services means assistance that strengthens an individual's or organization's ability to engage in continuous improvement and achieve expected outcomes. (NFP)

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes. (34 CFR 77.1)

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale. (34 CFR 77.1)

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (e.g., sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (e.g., assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (e.g., a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the

outcome is systematically related to the treatment. (34 CFR 77.1)

Fidelity means the delivery of instruction in the way in which it was designed to be delivered. (NFP)

Intensive, sustained TA means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels. (NFP)

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (i.e., the active "ingredients" that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes. (34 CFR 77.1)

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a "strong evidence base" or "moderate evidence base" for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a "positive effect" or "potentially positive effect" on a relevant outcome based on a "medium to large" extent of evidence, with no reporting of a "negative effect" or "potentially negative effect" on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (i.e., favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (e.g., State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy the requirement in this paragraph (iii)(D). (34 CFR 77.1)

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (e.g., training teachers on instructional practices for English learners and follow-on coaching for these teachers). (34 CFR 77.1)

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a “strong evidence base” or “moderate evidence base” for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a “positive effect” or “potentially positive effect” on a relevant outcome with no reporting of a “negative effect” or “potentially negative effect” on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (e.g., a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (i.e., favorable) effect on a relevant outcome. (34 CFR 77.1)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (e.g., establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks. (34 CFR 77.1)

Regional educational agency, for the purposes of this program, means “Tribal Educational Agency” as defined in ESEA section 6132(b)(3), as well as

other educational agencies that serve regional areas. (NFP)

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1)

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a “strong evidence base” for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a “positive effect” on a relevant outcome based on a “medium to large” extent of evidence, with no reporting of a “negative effect” or “potentially negative effect” on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (i.e., favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (e.g., State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement. (34 CFR 77.1)

TA services are defined as negotiated series of activities designed to reach a valued outcome. (NFP)

Targeted, specialized TA means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-

intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA. (NFP)

Third-party evaluator is an independent and impartial program evaluator who is contracted by the grantee to conduct an objective evaluation of the project. This evaluator must not have participated in the development or implementation of any project activities, except for the evaluation activities, nor have any financial interest in the outcome of the evaluation. (NFP)

Universal, general TA means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center’s website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA. (NFP)

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation. (34 CFR 77.1)

Program Authority: Section 203 of the Educational Technical Assistance Act of 2002 (ETAA) (20 U.S.C. 9602) and section 2244 of the ESEA (20 U.S.C. 6674).

Note: The project will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The NFP.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: \$1,475,000 in year one; \$1,500,000 in years two through five.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2022 from the list of unfunded applications from this competition.

Maximum Award: We will not make an award exceeding \$1,475,000 for a single budget period of 12 months in year one and \$1,500,000 for a single budget period of 12 months in years two through five.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* Research organizations, institutions, agencies, IHEs, or partnerships among such entities, or individuals, with the demonstrated ability or capacity to carry out the activities described in this notice, including regional entities that carried out activities under the Educational Research, Development, Dissemination, and Improvement Act of 1994 (as such Act existed on the day before November 5, 2002) and title XIII of the Elementary and Secondary Education Act of 1965 (as such title existed on the day before January 8, 2002).

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney

general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see www2.ed.gov/about/offices/list/ocfo/intro.html.

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to the Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. Under 34 CFR 75.708(e), a grantee may contract for supplies, equipment, and other services in accordance with 2 CFR part 200.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf, which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award/awards by the end of FY 2021.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.

- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.

- Use a font that is 12 point or larger.

- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses; and

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

(b) *Quality of project services (30 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are

members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework;

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice;

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services; and

(v) The extent to which the TA services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(c) *Quality of the project evaluation (20 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project;

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies;

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes; and

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) *Adequacy of resources and quality of project personnel (20 points).*

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the

applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator;

(ii) The qualifications, including relevant training and experience, of key project personnel;

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors;

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator;

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization;

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project;

(vii) The extent to which the budget is adequate to support the proposed project; and

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the management plan (20 points).*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks;

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project;

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project; and

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or

beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions, and under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this

competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

6. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification

(GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

www.ed.gov/fund/grant/apply/appforms/appforms.html.

5. *Performance Measures:* For the purposes of the Government Performance and Results Act of 1993 (GPRA) and reporting under 34 CFR 75.110, the Department will use the following measures to evaluate the effectiveness of the Center, as well as the Comprehensive Centers program as a whole:

- *Program Performance Measure 1:* The extent to which Comprehensive Center clients are satisfied with the quality, usefulness, and relevance of services provided.

- *Program Performance Measure 2:* The extent to which Comprehensive Centers provide services and products to a wide range of recipients.

- *Program Performance Measure 3:* The extent to which Comprehensive Centers demonstrate that capacity-building services were implemented as intended.

- *Program Performance Measure 4:* The extent to which Comprehensive Centers demonstrate recipient outcomes were met.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP and OESE.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

The Department will also closely monitor the extent to which the products and services provided by the Center meet needs identified by stakeholders and may require the Center to report on such alignment in their annual and final performance reports.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance

from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

David Cantrell,

Deputy Director, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

Ian Rosenblum,

Deputy Assistant Secretary for Policy and Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2021-14864 Filed 7-9-21; 11:15 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2021-SCC-0070]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Performance Report for Graduate Assistance in Areas of National Need (GAANN) Program

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 August 12, 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 Rebecca Ell, 202-453-6348.

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: Performance report for Graduate Assistance in Areas of National Need (GAANN) Program.

OMB Control Number: 1840-0748.

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: 291.

Total Estimated Number of Annual Burden Hours: 3,274.

Abstract: GAANN grantees must submit a performance report annually. In addition, grantees are required to submit a supplement to the final performance report two years after submission of their final report. The reports are used to evaluate grantee performance. Further, the data from the reports will be aggregated to evaluate the accomplishments and impact of the GAANN Program as a whole. Results will be reported to the Secretary in order to respond to GPRA requirements.

Dated: July 7, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021-14786 Filed 7-12-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Advanced Scientific Computing Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Advanced Scientific Computing Advisory Committee (ASCAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, July 29, 2021; 1:00 p.m. to 6:00 p.m. EDT.

ADDRESSES: **Teleconference:** Remote attendance of the ASCAC meeting will be possible via Zoom. Instructions will be posted on the Committee's website at: (<https://science.energy.gov/ascr/ascac/>) prior to the meeting and can also be obtained by contacting Christine Chalk by email at (christine.chalk@science.doe.gov), or by phone at (301) 903-7486.

FOR FURTHER INFORMATION CONTACT: Christine Chalk, Office of Advanced Scientific Computing Research; SC-31/ Germantown Building; U.S. Department of Energy; 1000 Independence Avenue SW; Washington, DC 20585-1290; Telephone (301) 903-7486; email: christine.chalk@science.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The Committee provides advice and guidance on a continuing basis to the Office of Science and to the Department of Energy on scientific priorities within the field of advanced scientific computing research.

Purpose of the Meeting: This meeting is the semi-annual meeting of the Committee.

Tentative Agenda:

- View from Washington
- View from Germantown
- Update on Exascale project activities
- Update on ASCR collaborations
- Update from Committee of Visitors
- Challenges and Best Practices for increasing Diversity
- Technical presentations
- Public Comment (10-minute rule)

The meeting agenda includes an update on the budget, accomplishments, and planned activities of the Advanced Scientific Computing Research program and the exascale computing project; an update from the Office of Science; technical presentations from funded researchers; updates from subcommittees and there will be an opportunity for comments from the public. The meeting will conclude at 6:00 p.m. EDT on July 29, 2021. Agenda updates and presentations will be posted on the ASCAC website prior to the meeting: <https://science.osti.gov/ascr/ascac>.

Public Participation: The meeting is open to the public. Individuals and representatives of organizations who would like to offer comments and suggestions may do so during the meeting. Approximately 30 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but will not exceed 10 minutes. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Those wishing to speak should submit your request at least five days before the meeting. Those not able to attend the meeting or who have insufficient time to address the committee are invited to send a written statement to Christine Chalk, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585; email to Christine.Chalk@science.doe.gov.

Minutes: The minutes of this meeting will be available within 90 days on the Advanced Scientific Computing website at: <https://science.osti.gov/ascr/ascac>.

Signed in Washington, DC, on July 8, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021-14856 Filed 7-12-21; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection

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

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE) gives notice of a request for public comment, pursuant to the Paperwork Reduction Act of 1995, on the continued collection of information entitled: *Budget Justification*, which DOE has developed for submission to and approval by the Office of Management and Budget (OMB).

DATES: Comments regarding this proposed information collection must be received on or before September 13, 2021. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments may be sent to U.S. Department of Energy, Golden Field Office, 15013 Denver West Parkway, Golden, CO 80401-3111, Attn: James Cash, or by email at james.cash@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to James Cash, U.S. Department of Energy, Golden Field Office, 15013 Denver West Parkway, Golden, CO 80401-3111, or by phone (240) 562-1456, or by email at james.cash@ee.doe.gov. The information collection instrument, titled "Budget Justification" may also be viewed at: <https://www.energy.gov/eere/funding/articles/eere-negotiation-forms>.

SUPPLEMENTARY INFORMATION: This information collection request contains:

- (1) OMB No.: 1910-5162, Budget Justification;
- (2) *Information Collection Request Title:* Budget Justification;
- (3) *Type of Request:* Renewal;
- (4) *Purpose:* This collection of

information is necessary in order for DOE to identify allowable, allocable, and reasonable recipient project costs eligible for Grants and Cooperative Agreements under Energy Efficiency and Renewable Energy (EERE) programs;

(5) *Annual Estimated Number of Respondents:* 400;

(6) *Annual Estimated Number of Total Responses:* 400;

(7) *Annual Estimated Number of Burden Hours:* 24 hours, per response;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* \$1,010.52 per one time response;

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Statutory Authority: Section 989(a) EPCA 2005 [Merit Review]{42 U.S.C. 16353(a)}; Section 646 DOE Organization Act [Contracts]{42 U.S.C. 7256(a)}; and 31 U.S.C. 503 (the Chief Financial Officers Act, Functions of the Deputy Director for Management), 31 U.S.C. 1111 (Improving Economy and Efficiency of the United States Government), 41 U.S.C. 1101-1131 (the Office of Federal Procurement Policy Act), Reorganization Plan No. 2 of 1970, and Executive Order 11541 ("Prescribing the Duties of the Office of Management and Budget and the Domestic Policy Council in the Executive Office of the President"), the Single Audit Act Amendments of 1996, (31 U.S.C. 7501-7507), as well as The Federal Program Information Act (Pub. L. 95-220 and Pub. L. 98-169, as amended, codified at 31 U.S.C. 6101-6106).

Signing Authority: This document of the Department of Energy was signed on July 7, 2021, by Derek G. Passarelli, Head of Contracting Activity and Director, Golden Field Office, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters

the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 8, 2021.

Treena V. Garrett,

*Federal Register Liaison Officer, U.S.
Department of Energy.*

[FR Doc. 2021-14838 Filed 7-12-21; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

[Case Number 2020-005; EERE-2020-BT-WAV-0022]

Energy Conservation Program: Decision and Order Granting a Waiver to Vinotemp International Corp. From the Department of Energy Walk-In Coolers and Walk-In Freezers Test Procedure

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

ACTION: Notification of decision and order.

SUMMARY: The U.S. Department of Energy (“DOE”) gives notification of a Decision and Order (Case Number 2020-005) that grants to Vinotemp International Corp. (“Vinotemp”) a waiver from specified portions of the DOE test procedure for determining the energy efficiency of specified walk-in cooler refrigeration systems. Due to the design of the specific basic models of walk-in refrigeration systems subject to this Decision and Order, the current test procedure evaluates such models in a manner that is unrepresentative of their energy use. Under the Decision and Order, Vinotemp is required to test and rate the specified basic models of its walk-in cooler refrigeration systems in accordance with the alternate test procedure set forth in the Decision and Order.

DATES: The Decision and Order is effective on July 13, 2021. The Decision and Order will terminate upon the compliance date of any future amendment to the test procedure for walk-in coolers and walk-in freezers located at title 10 of the Code of Federal Regulations (“CFR”), part 431, subpart R, appendix C that addresses the issues presented in this waiver. At such time, Vinotemp must use the relevant test procedure for this equipment for any testing to demonstrate compliance with the applicable standards, and any other representations of energy use.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000

Independence Avenue SW, Washington, DC 20585-0121. Email: AS_Waiver_Requests@ee.doe.gov.

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC-33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585-0103. Telephone: (202) 586-8145. Email: Michael.Kido@hq.doe.gov.

SUPPLEMENTARY INFORMATION: In accordance with § 431.401(f)(2) of title 10 of the Code of Federal Regulations (“CFR”) (10 CFR 431.401(f)(2)), DOE gives notification of the issuance of its Decision and Order as set forth below. The Decision and Order grants Vinotemp a waiver from the applicable test procedure at 10 CFR part 431, subpart R, appendix C for specified basic models of walk-in cooler refrigeration systems, and provides that Vinotemp must test and rate such walk-in cooler refrigeration systems using the alternate test procedure specified in the Decision and Order. Vinotemp’s representations concerning the energy efficiency of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy efficiency of these products. (42 U.S.C. 6314(d))

Manufacturers not currently distributing equipment in commerce in the United States that employ a technology or characteristic that results in the same need for a waiver from the applicable test procedure must petition for and be granted a waiver prior to the distribution in commerce of that equipment in the United States. Manufacturers may also submit a request for interim waiver pursuant to the requirements of 10 CFR 431.401. (10 CFR 431.401(j))

Case # 2020-005

Decision and Order

I. Background and Authority

The Energy Policy and Conservation Act, as amended (“EPCA”),¹ authorizes the U.S. Department of Energy (“DOE”) to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291-6317) Title III, Part C² of EPCA

¹ All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116-260 (Dec. 27, 2020).

² For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A-1.

established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve the energy efficiency for certain types of industrial equipment. This equipment includes walk-in coolers and walk-in freezers (collectively, “walk-ins”), the focus of this document. (42 U.S.C. 6311(1)(G))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316; 42 U.S.C. 6299).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered walk-ins. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of walk-ins during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for walk-ins is set forth in the Code of Federal Regulations (“CFR”) at 10 CFR part 431, subpart R, appendix C, *Uniform Test Method for the Measurement of Net Capacity and AWEF of Walk-in Cooler and Walk-in Freezer Refrigeration Systems* (“Appendix C”).

Any interested person may submit a petition for waiver from DOE’s test procedure requirements. 10 CFR 431.401(a)(1). DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design

characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. *Id.*

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 431.401(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule to that effect. *Id.* When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 431.401(h)(3).

II. Vinotemp's Petition for Waiver: Assertions and Determinations

DOE received correspondence from Vinotemp, docketed on June 29, 2020, seeking an interim waiver from the DOE test procedure applicable to walk-ins set forth in Appendix C for certain basic models Vinotemp characterized as "wine cellar" systems. (Vinotemp, No. 1)³ By letter docketed on December 10, 2020, Vinotemp submitted a petition for waiver for certain basic models of walk-in cooler refrigeration systems to supplement its original interim waiver request (Vinotemp, No. 3).⁴ The December 10, 2020 submission also explicitly stated that none of the basic models could operate below 45 °F and provided external static pressure ("ESP") values for the subject basic models.⁵ Vinotemp included additional basic models and clarified the specified external static pressure values as

maximum values (rather than tested values) for the specified basic models in an updated petition for interim waiver, received on March 11, 2021 (Vinotemp, No. 10). Vinotemp stated that the specified basic models of walk-in cooler refrigeration systems operate at a temperature range of 45 °F to 65 °F and 50 to 70 percent relative humidity ("RH"), rather than the 35 °F with less than 50 percent RH test conditions prescribed by the test procedure for walk-in cooler applications. Vinotemp stated that the units operate at temperature and relative humidity ranges optimized for long-term storage of wine, reflecting conditions in natural caves, and that they are usually located in air-conditioned spaces. Vinotemp asserted that the specified units cannot operate at 35 °F.

On May 4, 2021, DOE published a notification announcing its receipt of the petition for waiver and granted Vinotemp an interim waiver. 86 FR 23692 ("Notification of Petition for Waiver"). In the Notification of Petition for Waiver, DOE noted that the "Self-contained" and "Self-packaged" basic models of walk-in refrigeration systems identified by Vinotemp in its petition are self-contained, single-package systems. Although not specifically addressed in Vinotemp's request for waiver, DOE notes that operating a wine cellar at the 35 °F condition would adversely mechanically alter the intended performance of the system, which would include icing of the evaporator coil that could potentially damage the compressor, and would not result in an accurate representation of the performance of the cooling unit. 86 FR 23692, 23695. Additionally, although not explicitly identified by Vinotemp, DOE recognized that because of their single-package design, these basic models have insufficient space within the units and insufficient lengths of liquid line and evaporator outlet line for the dual mass flow meters (*i.e.*, two independent meters) and the dual temperature and pressure measurements (*i.e.*, two independent sets of measuring equipment) required by the test procedure's refrigerant enthalpy method. *Id.* AHRI 1250–2009 ("Standard for Performance Rating of Walk-in Coolers and Freezers")⁶—the industry testing standard on which DOE's test procedure is based—does not include specific provisions for testing single-package systems, and testing these basic models using the refrigerant enthalpy method as required by Appendix C would require extensive

additional piping to route the pipes out of the system—where the components could be installed—and then back in. This additional piping would impact unit performance, would likely be inconsistent between test labs, and would result in unrepresentative test values for the unit under test. AHRI has published a revised version of the test standard that provides provisions for single-package systems without requiring extensive additional piping (AHRI 1250–2020, *2020 Standard for Performance Rating of Walk-in Coolers and Freezers*).

In the Notification of Petition for Waiver, DOE established an alternate test procedure that was a modified version of the alternate test procedure suggested by Vinotemp. 86 FR 23692, 23698–23700. The alternate test procedure prescribed in the Notification of Petition for Waiver is the same as the alternate test procedure established in other waivers and interim waivers granted by DOE for similarly situated equipment.⁷ Specifically, the required alternate test procedure establishes unit cooler air inlet conditions of 55 °F and 55 percent RH, specifies primary and secondary capacity measurement methods for single-package systems, requires testing at 50 percent of maximum external static pressure for ducted units, and defines wine cellar box load and evaporator cycle periods for calculation of Annual Walk-in Energy Factor ("AWEF") for the specified basic models of walk-in cooler refrigeration systems. *Id.* DOE solicited comments from interested parties on all aspects of the petition and the modified alternate test procedure. *Id.*

DOE received one comment, which was submitted by the Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison (collectively, "the CA IOUs").⁸ The CA IOUs stated their agreement with DOE that since the subject basic models are unable to operate below 45 °F, there is limited opportunity for market confusion from labeling the products tested according to the test procedure waivers as walk-in coolers. (CA IOUs, No. 12)

For the reasons explained here and in the Notification of Petition for Waiver, absent a waiver the basic models identified by Vinotemp in its petition

³ A notation in the form "Vinotemp, No. 1" identifies a written submission: (1) Made by Vinotemp; and (2) recorded in document number 1 that is filed in the docket of this petition for waiver (Docket No. EERE–2020–BT–WAV–0022) and available at www.regulations.gov.

⁴ The waiver process under 10 CFR 431.401 requires that a petition for interim waiver must reference the related petition for waiver. (10 CFR 431.401(b)(2))

⁵ The December 10, 2020 update was consistent with a letter from the Air-Conditioning, Heating, and Refrigeration Institute ("AHRI") recommending that a 45 °F minimum temperature be used for testing wine cellar cooling systems, and that testing be conducted at an external static pressure ("ESP") value equal to 50 percent of the maximum ESP to be specified by manufacturers for each basic model. The AHRI letter is available at Docket No. EERE–2020–BT–WAV–0022–0002.

⁶ This also includes the related Errata sheet published by AHRI, dated December 2015.

⁷ See Notice of Decision and Order granting a waiver to Vintotheque (Case No. 2019–011; 86 FR 26504 (May 14, 2021); Notice of Decision and Order granting a waiver to CellarPro (Case No. 2019–009; 86 FR 26496 (May 14, 2021); and Notice of Decision and Order granting a waiver to Air Innovations (Case No. 2019–010; 86 FR 23702 (May 4, 2021)).

⁸ Comment available in Docket No. EERE–2020–BT–WAV–0022 at www.regulations.gov.

cannot be tested and rated for energy consumption on a basis representative of their true energy consumption characteristics. As noted previously, the alternate test procedure prescribed in the Interim Waiver modified Vinotemp's suggested alternate test procedure by including ESP provisions for certain systems that can be installed with (1) ducted evaporator air, (2) with or without ducted evaporator air, (3) ducted condenser air, or (4) with or without ducted condenser air. For such systems, testing is conducted at 50 percent of the maximum ESP specified by the manufacturer, subject to a tolerance of $-0.00/+0.05$ inches of water column ("in. wc."). (Vinotemp, No. 2)

Selection of a representative ESP equal to half the maximum ESP is based on the expectation that most installations will require less than the maximum allowable duct length. In the absence of field data, DOE expects that a range of duct lengths from the minimal length to the maximum allowable length would be used; thus, half of the maximum ESP would be representative of most installations.

If the basic model provides multiple condenser or unit cooler fan speed settings, the speed setting used is as instructed in the unit's installation instructions. However, if the installation instructions do not specify a fan speed setting for ducted installation, systems that can be installed with ducts would be tested with the highest available fan speed. The ESP is set for testing either by symmetrically restricting the outlet duct or, if using the indoor air enthalpy method, by adjusting the airflow measurement apparatus blower.

The alternate test procedure also specifies the requirements for measuring ESP consistent with the provisions provided in AHRI 1250–2020 when using the indoor air enthalpy method with unit coolers.

Additionally, the alternate test procedure requires that specified basic models that are split systems must be tested as matched pairs. According to Vinotemp's petition, the walk-in refrigeration system basic models that are split-systems are sold as full systems (*i.e.*, matched pairs) rather than as individual unit cooler and condensing unit components. This Order provides no direction regarding refrigerant line connection operating conditions, and as such is inapplicable to testing the basic models as individual components.

Consequently, this Order addresses only matched-pair testing of the specified basic models that are split-systems.

Contrary to Vinotemp's request, the Order does not modify the condenser air entering dry bulb temperature for outdoor condensers. 86 FR 23692, 23697. Vinotemp had suggested a 90 °F condenser air entering dry bulb temperature in its waiver request; however, the company did not provide technical justification for this request, and DOE has determined that outdoor wine cellar refrigeration units must be tested at 95 °F, 59 °F, and 35 °F, consistent with the current DOE test procedure.

For the reasons explained in the Notification of Petition for Waiver, the Order does not include a 0.55 correction factor in the alternate test procedure as suggested by Vinotemp. 86 FR 23692, 23697–23698. The company had observed that the test procedure in appendix A to subpart B of 10 CFR part 430 ("Appendix A"), which applies to miscellaneous refrigeration products, includes such a factor to adjust for average use, and sought to include such a factor as part of its petition. As explained in the Notice of Petition for Waiver, the closed-door conditions on which the miscellaneous refrigeration correction factor is based are not present in the test procedure for walk-in cooler refrigeration systems, and the referenced AHRI 1250–2009 provisions assume a load factor of 50 percent, consistent with Appendix C. *Id.* As a result, applying the 0.55 correction factor as suggested by Vinotemp is not appropriate for the specified basic models.

DOE is requiring that Vinotemp test and rate specified wine cellar walk-in refrigeration system basic models according to the alternate test procedure specified in this Decision and Order. This alternate procedure is a modified version of the one suggested by Vinotemp. The alternate test procedure required under this Order is the same alternate test procedure prescribed in the Interim Waiver Order.

This Decision and Order applies only to the basic models listed and does not extend to any other basic models. DOE evaluates and grants waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. Vinotemp may request that DOE extend the scope of this waiver to include additional basic models that employ the

same technology as those listed in this waiver. 10 CFR 431.401(g). Vinotemp may also submit another petition for waiver from the test procedure for additional basic models that employ a different technology and meet the criteria for test procedure waivers. 10 CFR 431.401(a)(1).

DOE notes that it may modify or rescind the waiver at any time upon DOE's determination that the factual basis underlying the petition for waiver is incorrect, or upon a determination that the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, Vinotemp may request that DOE rescind or modify the waiver if the company discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

As set forth previously, the test procedure specified in this Decision and Order is not the same as the test procedure suggested by Vinotemp. If Vinotemp believes that the alternate test method it suggested provides representative results and is less burdensome than the test method required by this Decision and Order, Vinotemp may submit a request for modification under 10 CFR 431.401(k)(2) that addresses the concerns that DOE has specified with that procedure. Vinotemp may also submit another less burdensome alternative test procedure not expressly considered in this notification under the same provision.

III. Order

After careful consideration of all the material that was submitted by Vinotemp, the various public-facing materials (*e.g.*, marketing materials, product specification sheets, and installation manuals) for the units identified in the petition, information provided by Vinotemp and other wine cellar walk-in refrigeration system manufacturers in meetings with DOE, and the comment received, in this matter, it is *ordered* that:

(1) Vinotemp must, as of the date of publication of this Order in the **Federal Register**, test and rate the following Wine Mate-branded wine cellar walk-in cooler refrigeration system basic models with the alternate test procedure as set forth in paragraph (2):

VINOTEMP BASIC MODELS

Brand name	Configuration	Basic model No.
Wine Mate	Single-Packaged	WM-2500HZD.
Wine Mate	Single-Packaged	WM-4500HZD.
Wine Mate	Single-Packaged	WM-6500HZD.
Wine Mate	Single-Packaged	WM-8500HZD.
Wine Mate	Single-Packaged	WM-4510HZD.
Wine Mate	Single-Packaged	WM-6510HZD.
Wine Mate	Single-Packaged	WM-8510HZD.
Wine Mate	Single-Packaged	WM-4500DS.
Wine Mate	Single-Packaged	WM-6500DS.
Wine Mate	Single-Packaged	WM-8500DS.
Wine Mate	Single-Packaged	WM-12030DS.
Wine Mate	Matched	WM-2500SSA.
Wine Mate	Matched	WM-2500SSD.
Wine Mate	Matched	WM-2500SSH.
Wine Mate	Matched	WM-2500SSL.
Wine Mate	Matched	WM-2500SSI.
Wine Mate	Matched	WM-2500SSO.
Wine Mate	Matched	WM-2500SSR.
Wine Mate	Matched	WM-2500SSV.
Wine Mate	Matched	WM-2500SSW.
Wine Mate	Matched	WM-4500SSA.
Wine Mate	Matched	WM-4500SSD.
Wine Mate	Matched	WM-4500SSH.
Wine Mate	Matched	WM-4500SSL.
Wine Mate	Matched	WM-4500SSI.
Wine Mate	Matched	WM-4500SSO.
Wine Mate	Matched	WM-4500SSR.
Wine Mate	Matched	WM-4500SSS.
Wine Mate	Matched	WM-4500SSV.
Wine Mate	Matched	WM-4500SSW.
Wine Mate	Matched	WM-6500SSA.
Wine Mate	Matched	WM-6500SSD.
Wine Mate	Matched	WM-6500SSH.
Wine Mate	Matched	WM-6500SSL.
Wine Mate	Matched	WM-6500SSR.
Wine Mate	Matched	WM-6500SSV.
Wine Mate	Matched	WM-8500SSA.
Wine Mate	Matched	WM-8500SSD.
Wine Mate	Matched	WM-8500SSH.
Wine Mate	Matched	WM-8500SSL.
Wine Mate	Matched	WM-8500SSS.
Wine Mate	Matched	WM-12000SSA.
Wine Mate	Matched	WM-12000SSD.
Wine Mate	Matched	WM-12000SSH.
Wine Mate	Matched	WM-12000SSS.

(2) The alternate test procedure for the Vinotemp basic models listed in paragraph (1) of this Order is the test procedure for Walk-in Cooler Refrigeration Systems prescribed by DOE at 10 CFR part 431, subpart R, appendix C, (“Appendix C to Subpart R”) with the modifications provided below. All other requirements of Appendix C and DOE’s other relevant regulations remain applicable.

In Appendix C to Subpart R, revise section 3.1.1 (which specifies modifications to AHRI 1250–2009 (incorporated by reference; see § 431.303)) to read:

3.1.1. In Table 1, Instrumentation Accuracy, refrigerant temperature measurements shall have an accuracy of ± 0.5 °F for unit cooler in/out. Measurements used to determine temperature or water vapor content of the air (*i.e.*, wet bulb or dew point) shall be accurate to within ± 0.25 °F; all other

temperature measurements shall be accurate to within ± 1.0 °F.

In Appendix C to Subpart R, revise section 3.1.4 (which specifies modifications to AHRI 1250–2009) and add modifications of AHRI 1250–2009 Tables 3 and 4 to read:

3.1.4. In Tables 3 and 4 of AHRI 1250–2009, Section 5, the Condenser Air Entering Wet-Bulb Temperature requirement applies only to single-packaged dedicated systems. Tables 3 and 4 shall be modified to read:

TABLE 3—FIXED CAPACITY MATCHED REFRIGERATOR SYSTEM AND SINGLE-PACKAGED DEDICATED SYSTEM, CONDENSING UNIT LOCATED INDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, % ¹	Condenser air entering dry-bulb, °F	Maximum condenser air entering wet-bulb, °F	Compressor status	Test objective
Evaporator Fan Power	55	55				Measure fan input wattage ² .
Refrigeration Capacity	55	55	90	³ 65	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.

Notes:

¹ The test condition tolerance (maximum permissible variation of the average value of the measurement from the specified test condition) for relative humidity is 3%.

² Measure fan input wattage either by measuring total system power when the compressor and condenser are turned off or by separately submetering the evaporator fan.

³ Maximum allowable value for Single-Packaged Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

TABLE 4—FIXED CAPACITY MATCHED REFRIGERATOR SYSTEM AND SINGLE-PACKAGED DEDICATED SYSTEM, CONDENSING UNIT LOCATED OUTDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, % ¹	Condenser air entering dry-bulb, °F	Maximum condenser air entering wet-bulb, °F	Compressor status	Test objective
Evaporator Fan Power	55	55				Measure fan input wattage ² .
Refrigeration Capacity A ...	55	55	95	³ 68	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Refrigeration Capacity B ...	55	55	59	³ 46	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler and system input power at moderate condition.
Refrigeration Capacity C ...	55	55	35	³ 29	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler and system input power at cold condition.

Notes:

¹ The test condition tolerance (maximum permissible variation of the average value of the measurement from the specified test condition) for relative humidity is 3%.

² Measure fan input wattage either by measuring total system power when the compressor and condenser are turned off or by separately submetering the evaporator fan.

³ Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

In Appendix C to Subpart R, following section 3.2.5 (instructions regarding modifications to AHRI 1250–2009), add sections 3.2.6 and 3.2.7 to read:

3.2.6 The purpose in section C1 of appendix C is modified by extending it to include Single-Packaged Dedicated Systems.

3.2.7 For general test conditions and data recording (appendix C, section C7), the test acceptance criteria in Table 2 and the data to be recorded in Table C2 apply to the Dual Instrumentation and Calibrated Box methods of test.

In Appendix C to Subpart R, revise section 3.3 to read:

3.3. *Matched systems, single-packaged dedicated systems, and unit coolers tested alone:* Test any split system wine cellar walk-in refrigeration system as a matched pair. Any condensing unit or unit cooler component must be matched with a corresponding counterpart for testing. Use the test method in AHRI 1250–2009 (incorporated by reference; see § 431.303), appendix C as the method of test for matched refrigeration systems, single-packaged dedicated systems, or unit coolers tested alone, with the following modifications:

* * * * *

In Appendix C to Subpart R, revise sections 3.3.3 through 3.3.3.2 to read:

3.3.3 *Evaporator fan power.*

3.3.3.1 The unit cooler fan power consumption shall be measured in accordance with the requirements in Section C3.5 of AHRI 1250–2009. This measurement shall be made with the fan operating at full speed, either measuring unit cooler or total system power input upon the completion of the steady state test when the compressors and condenser fan of the walk-in system is turned off, or by submetered measurement of the evaporator fan power during the steady state test.

Section C3.5 of AHRI 1250–2009 is revised to read:

Unit Cooler Fan Power Measurement. The following shall be measured and recorded during a fan power test.

$EF_{comp,on}$ Total electrical power input to fan motor(s) of Unit Cooler, W

FS Fan speed (s), rpm

N Number of motors

P_b Barometric pressure, in. Hg

T_{db} Dry-bulb temperature of air at inlet, °F

T_{wb} Wet-bulb temperature of air at inlet, °F

V Voltage of each phase, V

For a given motor winding configuration, the total power input shall be measured at the highest nameplated voltage. For three-phase power, voltage imbalance shall be no more than 2%.

3.3.3.2 Evaporator fan power for the off-cycle is equal to the on-cycle evaporator fan power with a run time of ten percent of the off-cycle time.

$EF_{comp,off} = 0.1 \times EF_{comp,on}$

In Appendix C to Subpart R, following section 3.3.7.2, add new sections 3.3.8, 3.3.9, and 3.3.10 to read:

3.3.8. Measure power and capacity of single-packaged dedicated systems as described in sections C4.1.2 and C9 of AHRI 1250–2020. The third and fourth sentences of Section C9.1.1.1 of AHRI 1250–2020 (“Entering air is to be sufficiently dry as to not produce frost on the Unit Cooler coil. Therefore, only sensible capacity measured by dry bulb change shall be used to calculate capacity.”) shall not apply.

3.3.9. For systems with ducted evaporator air, or that can be installed with or without ducted evaporator air: Connect ductwork on both the inlet and outlet connections and determine external static pressure as described in ASHRAE 37–2009, sections 6.4 and 6.5. Use pressure measurement instrumentation as described in ASHRAE 37–2009 section 5.3.2. Test at the fan speed specified in manufacturer installation instructions—if there is more than one fan speed setting and the installation instructions do not specify which speed to use, test at the highest speed. Conduct tests with the external static pressure equal to 50 percent of the maximum external static pressure allowed by the manufacturer for system installation within a tolerance of $-0.00/+0.05$ in. wc. If testing with the indoor air enthalpy method, adjust the airflow measurement apparatus fan to set the external static pressure—otherwise, set the external static pressure by symmetrically restricting the outlet of the test duct. In case of conflict, these requirements for setting evaporator airflow take precedence over airflow values specified in manufacturer installation instructions or product literature.

3.3.10. For systems with ducted condenser air, or that can be installed with or without ducted condenser air: Connect ductwork on both the inlet and outlet connections and determine external static pressure as described in ASHRAE 37–2009, sections 6.4 and 6.5. Use pressure measurement instrumentation as described in ASHRAE 37–2009 section 5.3.2. Test at the fan speed specified in manufacturer

installation instructions—if there is more than one fan speed setting and the installation instructions do not specify which speed to use, test at the highest speed. Conduct tests with the external static pressure equal to 50 percent of the maximum external static pressure allowed by the manufacturer for system installation within a tolerance of $-0.00/+0.05$ in. wc. If testing with the outdoor enthalpy method, adjust the airflow measurement apparatus fan to set the external static pressure—otherwise, set the external static pressure by symmetrically restricting the outlet of the test duct. In case of conflict, these requirements for setting condenser airflow take precedence over airflow values specified in manufacturer installation instructions or product literature. If testing using the outdoor air enthalpy method, the requirements of section 8.6 of ASHRAE 37–2009 are not applicable.

In Appendix C to Subpart R, revise section 3.3.6 (which specifies modifications to AHRI 1250–2009) to read:

3.3.6. AWEF is calculated on the basis that walk-in box load is equal to half of the system net capacity, without variation according to high and low load periods and without variation with outdoor air temperature for outdoor refrigeration systems, and the test must be done as a matched or single-package refrigeration system, as follows:

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For Indoor Condensing Units:

$$\dot{B}L = 0.5 \cdot \dot{q}_{ss}(90^\circ F)$$

$$LF = \frac{\dot{B}L + 3.412 \cdot \dot{E}F_{comp,off}}{\dot{q}_{ss}(90^\circ F) + 3.412 \cdot \dot{E}F_{comp,off}}$$

$$AWEF = \frac{\dot{B}L}{\dot{E}_{ss}(90^\circ F) \cdot LF + \dot{E}F_{comp,off} \cdot (1 - LF)}$$

For Outdoor Condensing Units:

$$\dot{B}L = 0.5 \cdot \dot{q}_{ss}(95^\circ F)$$

$$LF(t_j) = \frac{\dot{B}L + 3.412 \cdot \dot{E}F_{comp,off}}{\dot{q}_{ss}(t_j) + 3.412 \cdot \dot{E}F_{comp,off}}$$

$$AWEF = \frac{\sum_{j=1}^n BL(t_j)}{\sum_{j=1}^n E(t_j)}$$

$$BL(t_j) = \dot{B}L \cdot n_j$$

$$E(t_j) = \left[\dot{E}_{ss}(t_j) \cdot LF(t_j) + \dot{E}F_{comp,off} \cdot (1 - LF(t_j)) \right] \cdot n_j$$

Where:

$\dot{B}L$ is the non-equipment-related box load

LF is the load factor

And other symbols are as defined in AHRI 1250–2009.

(3) *Representations*. Vinotemp may not make representations about the efficiency of a basic model listed in paragraph (1) of this Order for compliance, marketing, or other purposes unless the basic model has been tested in accordance with the provisions set forth above and such representations fairly disclose the results of such testing.

(4) This waiver shall remain in effect according to the provisions of 10 CFR 431.401.

(5) This Order is issued on the condition that the statements, representations, and information provided by Vinotemp are valid. If Vinotemp makes any modifications to the controls or configurations of a basic model subject to this Order, such modifications will render the waiver invalid with respect to that basic model, and Vinotemp will either be required to

use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, Vinotemp may request that DOE rescind or modify the waiver if Vinotemp discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) Vinotemp remains obligated to fulfill any applicable requirements set forth at 10 CFR part 429.

DOE makes decisions on waivers and interim waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. Vinotemp may submit a new or amended petition for waiver and request

for grant of interim waiver, as appropriate, for additional basic models of walk-in cooler refrigeration systems. Alternatively, if appropriate, Vinotemp may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition consistent with 10 CFR 431.401(g).

Signing Authority

This document of the Department of Energy was signed on July 7, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the

document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 8, 2021.

Treena V. Garrett,

*Federal Register Liaison Officer, U.S.
Department of Energy.*

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BILLING CODE 6450-01-C

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for OMB review and comment.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Labor Relations Report collection. The collection requests information from the Department of Energy Management and Operation (M&O) and Facilities Management Contractors for contract administration, management oversight, and cost control. The information collection will assist the Department in evaluating the implementation of the contractors' work force collective bargaining agreements, and apprise the Department of significant labor-management developments at DOE contractor sites. This information is used to ensure that Department contractors maintain good labor relations and retain a workforce in accordance with the terms of their contract and in compliance with statutory and regulatory requirements as identified by contract.

DATES: Comments regarding this collection must be received on or before September 13, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments should be sent to: John M. Sullivan, GC-63, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, or by fax at (202) 586-0971; or by email to john.m.sullivan@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to: John M. Sullivan, Attorney-Advisor (Labor), GC-63, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, or by fax at (202) 586-0971 or by email to john.m.sullivan@hq.doe.gov.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.*: 1910-5143; (2) *Information Collection Request Title*: Labor Relations Report; (3) *Type of Request*: *Renewal*; (4) *Purpose*: The proposed collection will request information from the Department of Energy M&O and Facilities Management Contractors for contract administration, management oversight, and cost control. This information is used to ensure that Department contractors maintain good labor relations and retain a workforce in accordance with the terms of their contract and in compliance with statutory and regulatory requirements as identified by contract. The respondents are Department M&O and Facility Management Contractors; (5) *Annual Estimated Number of Respondents*: 35; (6) *Annual Estimated Number of Total Responses*: 35; (7) *Annual Estimated Number of Burden Hours*: 1.84 per respondent for total of 64.4 per year; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: \$5,964.95. *Statutory Authority*: 42 U.S.C. 7254, 7256.

Signing Authority

This document of the Department of Energy was signed on July 6, 2021, by John T. Lucas, Deputy General Counsel for Transactions, Technology and Contractor Human Resources, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 8, 2021.

Treena V. Garrett,

*Federal Register Liaison Officer, U.S.
Department of Energy.*

[FR Doc. 2021-14855 Filed 7-12-21; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18-103-000]

Rockies Express Pipeline LLC; Notice of Extension of Time Request

Take notice that on June 23, 2021, Rockies Express Pipeline LLC (Rockies Express) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until September 20, 2023, to complete the construction of six new 5,350 horsepower (hp) natural gas reciprocating compressor units (32,100 hp total) at its existing Cheyenne Compressor Station (Cheyenne Hub Enhancement Project) in Weld County, Colorado, as authorized as part of the Cheyenne Hub Enhancement Project in the September 20, 2019 Order Issuing Certificates¹ (September 20 Order). The September 20 Order required Rockies Express to complete construction and make the facilities available for service within two years of the Order date. Rockies Express has since completed construction of four of the six authorized compressor units, placing units 1-3 into service on July 26, 2020,² and unit 4 into service on December 17, 2020.³ Compressor units 5 and 6 remain unconstructed.

Rockies Express states it has been delayed in reaching full commercialization for compressor units 5 and 6, with the economic slowdown and fallout from the COVID-19 pandemic. The final two compressor units that have not yet been constructed will be installed at the existing Cheyenne Compressor Station on land already owned by Rockies Express under the terms and conditions of the existing certificate. Rockies Express states that the extension of time will not result in any environmental impacts not already examined on the record in the certificate proceeding and will provide Rockies Express with the time necessary to install these remaining two units.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Rockies Express' request for an extension of time may do so. No

¹ *Cheyenne Connector, LLC*, 168 FERC ¶ 61,180 (2019), *order amending certificate*, 171 FERC ¶ 61,055 (2020). In the Order the Commission also approved the Cheyenne Connector Pipeline Project in Docket No. CP18-102-000.

² Notice of Commencement of Service of Rockies Express Pipeline LLC, Docket No. CP18-103-000 (July 13, 2020).

³ Notice of Commencement of Service of Rockies Express Pipeline LLC, Docket No. CP18-103-000 (December 17, 2020).

reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10).⁴

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance.⁵ For those extension requests that are contested, the Commission will aim to issue an order acting on the request within 45 days.⁶ The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.⁷ The Commission will not consider arguments that re-litigate the issuance of the certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.⁸ At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.⁹ The OEP Director, or his or her designee, will act on all of those extension requests that are uncontested.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document 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. At this time, the Commission has suspended

access to Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and three copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on July 22, 2021.

Dated: July 7, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-14848 Filed 7-12-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP20-484-000; CP20-485-000]

ANR Pipeline Company; Great Lakes Transmission Limited Partnership; Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Alberta Xpress and Lease Capacity Abandonment Projects and Schedule for Environmental Review

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) for the Alberta Xpress and Lease Capacity Abandonment Projects (Projects), proposed by ANR Pipeline Company (ANR) and Great Lakes Transmission Limited Partnership (Great Lakes) in Evangeline Parish, Louisiana. The EIS will tier off Commission staff's Environmental Assessment (EA) and its findings and conclusions for the Project issued on December 4, 2020, and respond to comments filed on the EA.¹ The EIS will assist the Commission in its consideration of the Project's contribution to climate change and its decision-making process to determine

whether ANR and Great Lakes proposed Projects are in the public convenience and necessity. The schedule for preparation of the EIS is discussed in the "Schedule for Environmental Review" section of this notice.

The National Environmental Policy Act Process

The production of the EIS is part of the Commission's overall National Environmental Policy Act review process. Commission staff will independently analyze the proposed Project and prepare a draft EIS, which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any draft and final EIS will be available in electronic format in the public record through eLibrary² and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environmental/environmental-documents>).

Schedule for Environmental Review

This notice identifies the Commission staff's planned schedule for completion of a final EIS for the Project, which is based on an issuance of the draft EIS in July 2020.

Issuance of Notice of Availability of the final EIS—October 29, 2021
90-day Federal Authorization Decision Deadline—January 27, 2022

If a schedule change becomes necessary for the final EIS, an additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Environmental Mailing List

This notice is being sent to the Commission's current environmental mailing list for the Project which includes federal, state, and local government representatives and agencies; Native American Tribes; elected officials; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project and includes a mailing address with their comments. Commission staff will update the

⁴ Only motions to intervene from entities that were party to the underlying proceeding will be accepted. *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 39 (2020).

⁵ Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2019).

⁶ *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 40 (2020).

⁷ *Id.* at P 40.

⁸ Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

⁹ *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 40 (2020).

¹ The EA for the Project is filed in Docket Nos. CP20-484-000 and CP20-485-000 under Accession No. 20201204-3004.

² For instructions on connecting to eLibrary, refer to the "Additional Information" section of this notice.

environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed Project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket numbers CP20–484–000 or CP20–485–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments. OR

(2) Return the attached “Mailing List Update Form” (appendix 1).

Additional Information

In order to receive notification of the issuance of the EIS and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

Additional information about the Project is available from the Commission’s Office of External Affairs, at (866) 208–6676, or on the FERC website at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on “General Search” and enter the docket number in the “Docket Number” field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Dated: July 7, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021–14846 Filed 7–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL21–89–000; QF21–629–000]

Hecate Energy Blair Road LLC; Notice of Petition for Declaratory Order

Take notice that on July 6, 2021, pursuant to Rule 207 of the Federal Energy Regulatory Commission’s (Commission) Rules of Practice and Procedure,¹ Hecate Energy Blair Road LLC (Blair or Petitioner), filed a petition for declaratory order (Petition) requesting that the Commission issue a declaratory order providing limited waiver of the filing requirements applicable to small power production facilities set forth in Section 292.203(a)(3) of the Commission’s regulations (QF Filing Requirement)² for the time-period beginning when its qualifying small power production facility was placed into operation on December 29, 2017, and ending on March 30, 2021, and when Blair filed a QF self-certification with respect to such facility (Gap Period), as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission’s Home Page (<http://ferc.gov>) using the “eLibrary” link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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 by the President on March 13, 2020. For

¹ 118 CFR 385.207 (2020).

² 18 CFR 292.203(a)(3).

assistance, contact the Federal Energy Regulatory Commission at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the “eFiling” link at <http://www.ferc.gov>. Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern time on August 5, 2021.

Dated: July 7, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021–14844 Filed 7–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP15–490–000, CP15–490–001, CP16–20–000]

Delfin LNG LLC; Notice of Request for Extension of Time

Take notice that on June 30, 2021, Delfin LNG LLC (Delfin) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until September 28, 2022, to construct and place into service the facilities that were authorized in the original certificate authorization issued on September 28, 2017 (Certificate Order).¹ The Certificate Order authorized certain “onshore facilities” that would be used exclusively to transport natural gas to Delfin’s deepwater port “offshore facilities” (collectively, the Project) in federal waters offshore Louisiana. The onshore facilities would be used to meet the requirements of the customers of the offshore facilities. The Certificate Order required Delfin to construct and place the facilities in service by September 28, 2019.

Delfin states that on June 21, 2019, it requested an extension of time until March 28, 2023 to complete the construction of the onshore facilities in conjunction with construction of the offshore facilities. Delfin states that on July 8, 2019, the Commission’s Office of

¹ *Delfin LNG LLC*, 160 FERC ¶ 61,130 (2017).

Energy Projects granted an extension of time until September 28, 2020 to construct the onshore facilities and make them available for service.

On June 25, 2020, Delphin requested an extension of time until September 28, 2021 to continue to construct the onshore facilities. Delphin explains that it was continuing to work to develop the Project, however, a variety of factors complicated the task of negotiating offtake agreements with potential customers. Delphin states that on July 15, 2020, via delegated order, the Commission granted an extension of time until September 28, 2021 to construct the onshore facilities and make them available for service. (2020 Extension)

Delphin states that since the 2020 Extension, it has continued to work to develop the Project. Additionally, Delphin asserts that economic conditions are recovering from the global coronavirus pandemic, and the spot and short-term market for the LNG have significantly improved. Delphin views these developments as a precursor for an improved longer-term market, which it asserts will support long-term LNG offtake contract(s). Accordingly, applicants request an extension of time until September 28, 2022 to complete construction of the onshore facilities and place them into service.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Delphin's request for an extension of time may do so. No reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10).²

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance. For those extension requests that are contested,³ the Commission will aim to issue an order acting on the request

within 45 days.⁴ The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.⁵ The Commission will not consider arguments that re-litigate the issuance of the certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.⁶ At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.⁷ The OEP Director, or his or her designee, will act on all of those extension requests that are uncontested.

In addition to publishing the full text of this document in the **Federal Register**, The Commission provides all interested persons an opportunity to view and/or print the contents of this document 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. At this time, the Commission has suspended access to Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and three copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on, July 22, 2021.

⁴ *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 40 (2020).

⁵ *Id.* at P 40.

⁶ Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

⁷ *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 40 (2020).

Dated: July 7, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-14845 Filed 7-12-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3253-015]

Mad River Power Associates; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 3253-015.

c. *Date Filed:* November 3, 2020.

d. *Applicant:* Mad River Power Associates (MRPA).

e. *Name of Project:* Campton Hydroelectric Project (project).

f. *Location:* On the Mad River in Grafton County, New Hampshire. The project occupies approximately 0.05 acre of federal land administered by the U.S. Forest Service.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Mr. Ian Clark, Mad River Power Associates, 1 Pepsi Way, Suite 6n75, Katonah, NY 10536; Phone at (914) 297-7645, or email at info@dichotomycapital.com.

i. *FERC Contact:* Amanda Gill, (202) 502-6773 or amanda.gill@ferc.gov.

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a

² Only motions to intervene from entities that were party to the underlying proceeding will be accepted. *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 39 (2020).

³ Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2019).

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. The first page of any filing should include docket number P-3253-015.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is ready for environmental analysis at this time.

The Council on Environmental Quality (CEQ) issued a final rule on July 15, 2020, revising the regulations under 40 CFR parts 1500-1518 that federal agencies use to implement the National Environmental Policy Act (NEPA) (see Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 FR 43,304). The Final Rule became effective on and applies to any NEPA process begun after September 14, 2020. Commission staff intends to conduct its NEPA review in accordance with CEQ's new regulations.

l. *Project Description:* The project consists of: (1) A 22-foot-wide, 24-foot-high concrete intake structure located approximately 60 feet upstream of the U.S. Forest Service's Campton Dam on the east shoreline of the U.S. Forest Service's Campton Pond, that includes a 25-foot-long, 13-foot-high trashrack with 1.75-inch clear bar spacing; (2) a 600-foot-long, 78-inch-diameter underground steel penstock that trifurcates into three 48-inch-diameter sections measuring 20 feet, 30 feet, and 43 feet in length, respectively; (3) a 43-foot-long, 30-foot-wide powerhouse located on the east side of the Mad River that contains a 167-kW Francis turbine-generator unit; (4) two 236-kW submersible Flygt turbine-generator units located outside of the powerhouse; (5) an approximately 55-foot-long, 40-foot-wide tailrace; (6) a 200-foot-long transmission line and a 33.5-kilovolt transformer that connects the generators to the electric grid; (7) an Atlantic salmon smolt bypass facility consisting

of an 85-foot-long, 20-inch diameter cast iron pipe that empties into a 3.5-foot-deep plunge pool approximately 15 feet downstream of the dam; and (8) appurtenant facilities. The project creates an approximately 600-foot-long bypassed reach of the Mad River.

The current license requires: (1) Inflow to be discharged over the spillway to the bypassed reach during periods of non-generation or when inflow is less than 25 cfs; (2) a minimum flow of 4.5 cfs through the Atlantic salmon smolt bypass facility during periods of generation or when inflow is greater than 25 cfs; and (3) operation of the smolt bypass facility from mid-April to mid-June. The average annual generation of the project is currently approximately 1,170 megawatt-hours (MWh).

MRPA proposes to: (1) Continue operating the project in a run-of-release mode; (2) replace one of the 236-kW Flygt turbine-generator units with a new 340-kW Flygt turbine-generator unit, for a total installed capacity of 743 kW at the project; (2) release a minimum flow of 29 cfs or inflow, whichever is less, over the dam to the bypassed reach; and (3) close the existing smolt bypass facility. MRPA estimates that the average annual generation of the proposed project will be approximately 1,900 MWh.

m. A copy of the application can be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

All filings must: (1) Bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions, or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

You may also register online at <https://www.ferc.gov/ferc-online/overview> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. The applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification. Please note that the certification request must comply with 40 CFR 121.5(b), including documentation that a pre-filing meeting request was submitted to the certifying authority at least 30 days prior to submitting the certification request. Please also note that the certification request must be sent to the certifying authority and to the Commission concurrently.

o. *Procedural Schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Deadline for filing comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions.	September 2021.
Deadline for filing reply comments.	October 2021.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: July 7, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-14843 Filed 7-12-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meetings

TIME AND DATE: July 15, 2021, 10:00 a.m.

PLACE: Open to the public via audio Webcast only. Join FERC online to listen live at <http://ferc.capitolconnection.org/>.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* *Note*—Items listed on the agenda may be deleted without further notice.

This is a list of matters to be considered by the Commission. It does

not include a listing of all documents relevant to the items on the agenda. All

public documents, however, may be viewed on line at the Commission's

website at <https://elibrary.ferc.gov/eLibrary/search> using the eLibrary link.

1081ST—MEETING—OPEN MEETING

[July 15, 2021, 10:00 a.m.]

Item No.	Docket No.	Company
Administrative		
A-1	AD21-1-000	Agency Administrative Matters.
A-2	AD21-2-000	Customer Matters, Reliability, Security and Market Operations.
Electric		
E-1	RM21-17-000	Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection.
E-2	ER18-1639-000	Constellation Mystic Power, LLC.
E-3	EL20-59-000	Duquesne Light Company v. PJM Interconnection, L.L.C.
E-4	ER20-2308-001	PJM Interconnection, L.L.C.
E-5	EL21-74-000	Nevada Power Company and Sierra Pacific Power Company v. California Independent System Operator Corporation.
E-6	ER20-2878-010	Pacific Gas and Electric Company.
E-7	EC21-77-000	FirstEnergy Corp.
E-8	EL21-49-000	Hecate Energy Greene County 3 LLC v. Central Hudson Gas & Electric Corporation and New York Independent System Operator, Inc.
E-9	EL21-42-000	Quincy-Columbia Basin Irrigation District and East Columbia Basin Irrigation District.
E-10	ER20-1068-000	The Dayton Power and Light Company.
E-11	EL20-63-000	City of Alameda, California v. Pacific Gas and Electric Company.
E-12	EL21-65-000	Holy Cross Electric Association, Inc.
Gas		
G-1	IN12-17-000	Total Gas & Power North America, Inc., Total, S.A., Total Gas & Power, Ltd., Aaron Hall and Therese Tran f/k/a/Nguyen.
G-2	RM20-14-001	Five-Year Review of the Oil Pipeline Index.
G-3	RM96-1-042	Standards for Business Practices of Interstate Natural Gas Pipelines.
G-4	RP21-741-000	DCP South Central Texas LLC.
G-5	RP21-722-000	Hartree Partners, LP v. Northern Natural Gas Company.
G-6	Omitted.	
G-7	RP20-908-003	Alliance Pipeline L.P.
Hydro		
H-1	P-405-129	Exelon Generation Company, LLC.
H-2	RM20-21-000	Removing Profile Drawing Requirement for Qualifying Conduit Notices of Intent and Revising Filing Requirements for Major Hydroelectric Projects 10 MW or Less.
H-3	P-2444-028	Northern States Power Company—Wisconsin.
Certificates		
C-1	Omitted.	
C-2	CP20-466-001	New Fortress Energy LLC.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502-8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502-8627.

The public is invited to listen to the meeting live at <http://ferc.capitolconnection.org/>. Anyone with internet access who desires to hear this event can do so by navigating to www.ferc.gov's Calendar of Events and locating this event in the Calendar. The event will contain a link to its audio webcast. The Capitol Connection provides technical support for this free

audio webcast. It will also offer access to this event via phone bridge for a fee. If you have any questions, visit <http://ferc.capitolconnection.org/> or contact Shirley Al-Jarani at 703-993-3104.

Issued: July 8, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-14948 Filed 7-9-21; 11:15 am]

BILLING CODE 6717-01-P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 37364]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a New Matching Program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended ("Privacy Act"), this document announces the establishment of a computer matching program the Federal

Communications Commission (“FCC” or “Commission” or “Agency”) and the Universal Service Administrative Company (USAC) will conduct with the Virginia Department of Social Services (Department). The purpose of this matching program is to verify the eligibility of applicants to and subscribers of the Emergency Broadband Benefit Program, which is administered by USAC under the direction of the FCC, or other federal programs that use qualification for the FCC’s Lifeline Program as an eligibility criterion. More information about this program is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before August 12, 2021. This computer matching program will commence on August 12, 2021, and will conclude 18 months after becoming effective.

ADDRESSES: Send comments to Margaret Drake, FCC, 45 L Street NE, Washington, DC 20554, or to Privacy@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Drake at 202–417–1707 or Privacy@fcc.gov.

SUPPLEMENTARY INFORMATION: The Emergency Broadband Benefit Program (EBBP) was established by Congress in the Consolidated Appropriations Act of 2021, Public Law 116–260, 134 Stat. 1182. EBBP is a program that will help low-income Americans obtain discounted broadband service and one-time co-pay for a connected device (laptop, desktop computer or tablet). This program was created specifically to assist American families’ access to broadband, which has proven to be essential for work, school, and healthcare during the public health emergency that exists as a result of COVID–19. A household may qualify for the EBBP benefit under various criteria, including an individual qualifying for the FCC’s Lifeline program.

In a Report and Order adopted on March 31, 2016, the Commission ordered USAC to create a National Lifeline Eligibility Verifier (“National Verifier”), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program. The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants’ eligibility for EBBP. The purpose of this matching program

is to verify the eligibility of EBBP applicants and subscribers by determining whether they receive Supplemental Nutrition Assistance Program (SNAP) and Medicaid benefits administered by the Virginia Department. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

Participating Non-Federal Agencies

Virginia Department of Social Services (Department).

Authority for Conducting the Matching Program

Consolidated Appropriations Act of 2021, Public Law 116–260, 134 Stat. 1182; 47 CFR part 54.

Purpose(s)

In the 2016 Lifeline Modernization Order, the FCC required USAC to develop and operate the National Verifier to improve efficiency and reduce waste, fraud, and abuse in the Lifeline program. The stated purpose of the National Verifier is “to increase the integrity and improve the performance of the Lifeline program for the benefit of a variety of Lifeline participants, including Lifeline providers, subscribers, states, community-based organizations, USAC, and the Commission.” 31 FCC Rcd 3962, 4006, para. 126. To help determine whether Lifeline applicants and subscribers are eligible for Lifeline benefits, the Order contemplates that the USAC-operated LED will communicate with information systems and databases operated by other Federal and State agencies. Id. at 4011–2, paras. 135–7.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants’ eligibility for EBBP. The purpose of this matching program is to verify the eligibility of EBBP applicants and subscribers by determining whether they receive SNAP and Medicaid benefits administered by the Virginia Department. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

Categories of Individuals

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for EBBP benefits; are currently receiving benefits; are individuals who enable another individual in their household to qualify for EBBP benefits; are minors whose status qualifies a parent or guardian for EBBP benefits; or are

individuals who have received EBBP benefits.

Categories of Records

The categories of records involved in the matching program include, but are not limited to last name, date of birth and the last four digits of the applicant’s Social Security Number. The National Verifier will transfer these data elements to the Virginia Department, which will respond either “yes” or “no” that the individual is enrolled in an EBBP-qualifying assistance program: State of Virginia’s SNAP and Medicaid.

System(s) of Records

The USAC records shared as part of this matching program reside in the EBBP system of records, FCC/WCB–3, Emergency Broadband Benefit Program, which was published in the **Federal Register** at 86 FR 11523 (Feb. 25, 2021).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–14961 Filed 7–9–21; 4:15 pm]

BILLING CODE 6712–01–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

[Docket No.: FMCS–2021–3]

Notice to Mediation Agency

AGENCY: Federal Mediation and Conciliation Service (FMCS).

ACTION: 60-Day notice and request for comments.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS), invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection request, Notice to Mediation Agency, (Agency Form F–7). This information collection request was previously approved by the Office of Management Budget (OMB) but has expired. FMCS is requesting a reinstatement without change. The Notice to Mediation Agency, (Agency Form F–7), allows parties to comply with their statutory obligation under the Labor Management Relations Act of 1947. The Agency Form F–7 also allows FMCS to receive these notices from parties to a collective bargaining agreement to comply with its statutory mandate to facilitate mediation.

DATES: Comments must be submitted on or before September 13, 2021.

ADDRESSES: You may submit comments [identified by Docket No.: FMCS–2021–3] through one of the following methods:

• *Email:* Arthur Pearlstein, apearlstein@fmcs.gov;
 • *Mail:* Arthur Pearlstein, HQ Office of Arbitration, One Independence Square, 250 E St SW, Washington, DC 20427. Please note that at this time, the FMCS office is not open for visitors and mail is not checked daily. Therefore, we encourage emailed comments.

FOR FURTHER INFORMATION CONTACT: Arthur Pearlstein, 202-606-8103, apearlstein@fmcs.gov.

SUPPLEMENTARY INFORMATION: Copies of the agency form are available here. Paper copies are available from the Office of Arbitration Services by emailing Arthur Pearlstein at the email address above. Please ask for Agency Form F-7.

I. Information Collection Request

Agency: Federal Mediation and Conciliation Service.

Form Number: OMB No. 3076-0004.

Type of Request: Reinstatement without change of a previously approved collection.

Affected Entities: Employers and their representatives; and labor unions, their representatives and employees, regarding contract negotiations.

Frequency: This form is completed once for resolution facilitation.

Abstract: Under the Labor Management Relations Act of 1947, 29 U.S.C. 158(d), Congress listed specific notice provisions so that no party to a collective bargaining agreement can terminate or modify a collective bargaining contract, unless the party wishing to terminate or modify the contract sends a written notice to the other party sixty days prior to the expiration date (29 U.S.C. 158(d)(1)) and offers to meet and confer with the other party for the purpose of negotiating a new or modified contract (29 U.S.C. 158(d)(2)). The Act requires that parties notify FMCS within thirty days after such notice of the existence of a bargaining dispute (29 U.S.C. 158(d)(3)). The 1974 amendments to the National Labor Relations Act extended coverage to nonprofit health care institutions, including similar notices to FMCS. 29 U.S.C. 158(d) and (g). To facilitate handling around 27,190 notices a year, FMCS created information collection form F-7. The purpose of this information collection activity is for FMCS to comply with its statutory duty to receive these notices, to facilitate assignment of mediators to assist in labor disputes, and to assist the parties in knowing whether proper notice was given. The information from these notices is sent electronically to the appropriate field manager who assigns

the cases to a mediator so that the mediator may contact labor and management quickly, efficiently, and offer dispute resolution services. Either party to a contract may make a request in writing for a copy of the notice filed with FMCS. Form F-7 was created to allow FMCS to gather desired information in a uniform manner. The collection of such information, including the name of the employer or employer association, address and phone number, email address, official contact, bargaining unit and establishment size, location of affected establishment and negotiations, industry, union address, phone number, email address and official contact, contract expiration date or renewal date, whether the notice is filed on behalf of the employer or the union, and whether this is a health care industry notice is critical for reporting and mediation purposes.

Burden: The current total annual burden estimate is that FMCS will receive requests from approximately 27,190 respondents per year. The form takes about 10 minutes to complete.

II. Request for Comments

FMCS solicits comments to:

- i. Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- ii. Enhance the accuracy of the agency's estimates of the burden of the proposed collection of information.
- iii. Enhance the quality, utility, and clarity of the information to be collected.
- iv. Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic collection technologies or other forms of information technology.

III. The Official Record

The official records are paper and electronic records. The paper records are maintained at the address at the beginning of this document.

Dated: July 8, 2021.

Sarah Cudahy,

General Counsel.

[FR Doc. 2021-14823 Filed 7-12-21; 8:45 am]

BILLING CODE 6732-01-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 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 July 28, 2021.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *The Ronald G. Chamberlin Irrevocable Trust, Nathan A. Wurm and Eric D. Wurm, as co-trustees, The Irrevocable Gifting Trust FBO Nathan A. Wurm, Nathan A. Wurm, as trustee, and The Irrevocable Gifting Trust FBO Eric D. Wurm, Eric D. Wurm, as trustee, all of Caledonia, Minnesota;* to join the Wurm Family Control Group, a group acting in concert, to retain voting shares of Eitzen Independents, Inc., Eitzen, Minnesota, and thereby indirectly retain voting shares of ESB Bank, Caledonia, Minnesota.

Board of Governors of the Federal Reserve System, July 7, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-14781 Filed 7-12-21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. The application under section 3 of the Bank Holding Company Act of 1956 by *First Bancorp of Taylorville, Inc., Taylorville, Illinois*, published on July 7, 2021 in 86 FR 35796 has been withdrawn.

Board of Governors of the Federal Reserve System, July 8, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-14861 Filed 7-12-21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 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 the BHC Act (12 U.S.C. 1842(c)).

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 August 11, 2021.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications)

2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Plains Bancorp, Inc., Dimmit, Texas*; to acquire Childress Bancshares, Inc., and thereby indirectly acquire First Bank & Trust Company, both of Childress, Texas.

Board of Governors of the Federal Reserve System, July 8, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-14876 Filed 7-12-21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 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 the BHC Act (12 U.S.C. 1842(c)).

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 August 12, 2021.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *MidCountry Acquisition Corp., Minneapolis, Minnesota*; to acquire McGregor Banco, Inc., and thereby indirectly acquire Grand Timber Bank, both of McGregor, Minnesota.

2. *The Heritage Bancshares Group, Inc. Employee Stock Ownership Plan and Trust, Spicer, Minnesota*; to become a bank holding company by acquiring 32.6 percent of the voting shares of Heritage Bancshares Group, Inc., and thereby indirectly acquiring voting shares of Heritage Bank, N.A., both of Spicer, Minnesota.

Board of Governors of the Federal Reserve System, July 8, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-14863 Filed 7-12-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE**GENERAL SERVICES ADMINISTRATION****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[OMB Control No. 9000-0010; Docket No. 2021-0053; Sequence No. 8]

Submission for OMB Review; Progress Payments (SF 1443)

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

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding progress payments (SF 1443).

DATES: Submit comments on or before August 12, 2021.

ADDRESSES: Written comments and recommendations for this 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 Review—Open for Public Comments" or by using the search function.

Additionally, submit a copy to GSA through <http://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000-0010, Progress Payments (SF 1443). Comments received generally will be posted without change to <http://>

www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, at telephone 202-969-7207, or email zenaida.delgado@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and any Associated Form(s)

9000-0010, Progress Payments (SF 1443), Standard Form 1443, Contractor's Request for Progress Payment.

B. Need and Uses

This clearance covers the information that contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

- *FAR 52.232-16, Progress Payments, and Standard Form (SF) 1443, Contractor's Request for Progress Payment.*

Paragraph (g) of this FAR clause requires contractors to furnish reports, certificates, financial statements, and other pertinent information (including estimates to complete) reasonably requested by contracting officers for the administration of fixed-price contracts under which the Government will provide progress payments based on costs. Each request for progress payment shall be submitted on a SF 1443.

Contracting officers use this information to administer progress payments under a contract. This collection of information is necessary for protection of the Government against financial loss through making of progress payments.

C. Annual Burden

Respondents: 11,804.

Total Annual Responses: 377,728.

Total Burden Hours: 158,646.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 86 FR 22207, on April 27, 2021. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite OMB

Control No. 9000-0010, Progress Payments (SF 1443).

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2021-14852 Filed 7-12-21; 8:45 am]

BILLING CODE 6820-EP-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2021-0067, NIOSH-342]

Draft—Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: NIOSH announces the availability of a draft technical report entitled *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report* now available for public comment. To view the notice and related materials, visit <https://www.regulations.gov> and enter CDC-2021-0067 in the search field and click "Search."

DATES: Electronic or written comments must be received by September 13, 2021.

ADDRESSES: You may submit comments, identified by CDC-2021-0067 and docket number NIOSH-342, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov> Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2021-0067; NIOSH-342]. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background

documents or comments received, go to <https://www.regulations.gov>. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT:

Nathan Drew, National Institute for Occupational Safety and Health, Emerging Technologies Branch, 1090 Tusculum Avenue, MS C-14, Cincinnati, OH 45226, telephone (513) 533-8352 (not a toll free number).

SUPPLEMENTARY INFORMATION: On December 17, 2019, the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention announced in the **Federal Register** [84 FR 68935] plans to evaluate the scientific data on engineered nanomaterials for the development of categorical occupational exposure limits. The draft NIOSH technical report describing approaches to evaluating these scientific data is now available for public comment, *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report*.

Background: Most chemical substances, including engineered nanomaterials, do not have specific occupational exposure limits. Alternative methods are needed to assess the potential occupational safety and health hazards of engineered nanomaterials. Categorical occupational exposure limits are one approach to estimating exposure concentrations for groups of materials with similar toxicological effects and/or physicochemical properties. Occupational exposure banding is another approach to protect worker health by assigning chemical substances into specific categories or "bands" based on their associated health outcomes and on potency considerations. These bands correspond to a range of airborne exposure concentrations to inform risk management decisions for substances that do not have occupational exposure limits. NIOSH has proposed an evidence-based approach to evaluate the scientific information available in order to derive occupational exposure limits, or bands, for engineered nanomaterials. This proposed approach is described in the draft NIOSH technical report available for public comment, *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report*. This draft report contains two main parts: (I) User Guide

and (II) full Technical Report and Appendixes.

The purpose of the public comment period is to obtain comments on the draft report. Comments are being sought from individuals including scientists and representatives from various government agencies, industry, labor, and other stakeholders, and also the public. If there are errors of fact, unsubstantiated claims, evidence of careless experimental work, inclusion of too much information already in the literature, or statements that are inaccurate, please note such in your review comments.

The authors ask that special emphasis be placed on technical review of the following issues:

1. Does the draft document adequately describe the process for gathering and evaluating the information available on occupational exposure limits or bands for engineered nanomaterials?
2. Does the draft document adequately describe the development of a framework for categorizing engineered nanomaterials by potential occupational health hazard from inhalation exposure?
3. Are the clustering and classification modeling methodologies reasonable for these data?
4. Is a revision to current occupational exposure banding guidance needed to incorporate a band F?
5. How useful and practical is the approach described in both the user guide and full technical report for deriving categorical occupational exposure limits, and what are the opportunities for improvement?
6. Are the current searches and collection of scientific data sufficient, and are there additional opportunities for obtaining data that were not included?
7. Would the methods used in the report also be appropriate for a future comprehensive dataset of experimental, toxicological, and physicochemical information for engineered nanomaterials?
8. Are there additional comments that you would like to provide?

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2021-14801 Filed 7-12-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-7063-N]

Announcement of the Advisory Panel on Outreach and Education (APOE) July 28, 2021 Virtual Meeting

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the APOE (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Health Insurance Marketplace®, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

DATES:

Meeting Date: Wednesday, July 28, 2021 from 12:00 p.m. to 5:00 p.m. eastern daylight time (e.d.t.).

Deadline for Meeting Registration, Presentations, Special Accommodations, and Comments: Wednesday, July 14, 2021, 5:00 p.m. (e.d.t.).

ADDRESSES:

Meeting Location: Virtual. All those who RSVP will receive the link to attend.

Presentations and Written Comments: Presentations and written comments should be submitted to: Lisa Carr, Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202-690-5742, or via email at APOE@cms.hhs.gov.

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register at the website <https://www.eventbrite.com/e/apoe-july-28-2021-virtual-meeting-tickets-151112584809> or by contacting the DFO listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should

contact the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Lisa Carr, Designated Federal Official, Office of Communications, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202-690-5742, or via email at APOE@cms.hhs.gov.

Additional information about the APOE is available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE>. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

I. Background and Charter Renewal Information

A. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of federal advisory committees. The Panel is authorized by section 1114(f) of the Social Security Act (the Act) (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) signed the charter establishing the Citizen's Advisory Panel on Medicare Education¹ (the predecessor to the APOE) on January 21, 1999 (64 FR 7899) to advise and make recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare education programs, including with respect to the Medicare+Choice (M+C) program added by the Balanced Budget Act of 1997 (Pub. L. 105-33).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) expanded the existing health plan options and benefits available under the M+C program and renamed it the Medicare Advantage (MA) program. CMS has had substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options available and better tools to evaluate these options. The successful MA program implementation required CMS to consider the views and policy input from a variety of private

¹ We note that the Citizen's Advisory Panel on Medicare Education is also referred to as the Advisory Panel on Medicare Education (65 FR 4617). The name was updated in the Second Amended Charter approved on July 24, 2000.

sector constituents and to develop a broad range of public-private partnerships.

In addition, Title I of the MMA authorized the Secretary and the Administrator of CMS (by delegation) to establish the Medicare prescription drug benefit. The drug benefit allows beneficiaries to obtain qualified prescription drug coverage. In order to effectively administer the MA program and the Medicare prescription drug benefit, we have substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options and benefits available, and to develop better tools to evaluate these plans and benefits.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the Affordable Care Act) expanded the availability of other options for health care coverage and enacted a number of changes to Medicare as well as to Medicaid and CHIP. Qualified individuals and qualified employers are now able to purchase private health insurance coverage through a competitive marketplace, called an Affordable Insurance Exchange (also called Health Insurance Marketplace[®], or Marketplace^{® 2}). In order to effectively implement and administer these changes, we must provide information to consumers, providers, and other stakeholders through education and outreach programs regarding how existing programs will change and the expanded range of health coverage options available, including private health insurance coverage through the Marketplace[®]. The APOE (the Panel) allows us to consider a broad range of views and information from interested audiences in connection with this effort and to identify opportunities to enhance the effectiveness of education strategies concerning the Affordable Care Act.

The scope of this Panel also includes advising on issues pertaining to the education of providers and stakeholders with respect to the Affordable Care Act and certain provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5).

On January 21, 2011, the Panel's charter was renewed and the Panel was renamed the Advisory Panel for

Outreach and Education. The Panel's charter was most recently renewed on January 19, 2021, and will terminate on January 19, 2023 unless renewed by appropriate action.

B. Charter Renewal

In accordance with the January 19, 2021, charter, the APOE will advise the HHS and CMS on developing and implementing education programs that support individuals who are enrolled in or eligible for Medicare, Medicaid, CHIP, or coverage available through the Health Insurance Marketplace[®] and other CMS programs. The scope of this FACA group also includes advising on education of providers and stakeholders with respect to health care reform and certain provisions of the HITECH Act enacted as part of the ARRA.

The charter will terminate on January 19, 2023, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The APOE is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

In accordance with the renewed charter, the APOE will advise the Secretary and the CMS Administrator concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid, the CHIP, and coverage available through the Health Insurance Marketplace[®] and other CMS programs.
- Enhancing the federal government's effectiveness in informing Medicare, Medicaid, CHIP, or the Health Insurance Marketplace[®] consumers, issuers, providers, and stakeholders, pursuant to education and outreach programs of issues regarding these programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers, partners and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, the CHIP and the Health Insurance Marketplace[®] education programs, and other CMS programs as designated.

- Assembling and sharing an information base of “best practices” for helping consumers evaluate health coverage options.
- Building and leveraging existing community infrastructures for information, counseling, and assistance.

- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of June 3, 2021, are: E. Lorraine Bell, Chief Officer, Population Health, Catholic Charities USA; Nazleen Bharmal, Medical Director of Community Partnerships, Cleveland Clinic; Julie Carter, Senior Federal Policy Associate, Medicare Rights Center; Scott Ferguson, Director of Care Transitions and Population Health, Mount Sinai St. Luke's Hospital; Leslie Fried, Senior Director, Center for Benefits Access, National Council on Aging; Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University; Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers; Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine; Cheri Lattimer, Executive Director, National Transitions of Care Coalition; Cori McMahon, Vice President, Tridium; Alan Meade, Director of Rehabilitation Services, Holston Medical Group; Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated; Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska; Morgan Reed, Executive Director, Association for Competitive Technology; Margot Savoy, Chair, Department of Family and Community Medicine, Temple University Physicians; Congresswoman Allyson Schwartz, President and CEO, Better Medicare Alliance; and; Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the July 28, 2021 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (May 26, 2021) meeting
- CMS programs, initiatives, and priorities

² Health Insurance Marketplace^{®SM} and Marketplace^{®SM} are service marks of the U.S. Department of Health and Human Services.

- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website <https://www.eventbrite.com/e/apoe-july-28-2021-virtual-meeting-tickets-151112584809> or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

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: June 30, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021-14830 Filed 7-12-21; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-2567]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is requesting that this information collection request (ICR), for revisions to the form CMS-2567 be processed under the emergency Paperwork Reduction Act of 1995 (PRA) clearance process.

DATES: Comments must be received by August 12, 2021.

ADDRESSES: When commenting, please reference the document identifier (CMS-2567) or OMB control number (0938-0391). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS-R-39/OMB Control Number 0938-0365, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

FOR FURTHER INFORMATION CONTACT: William Parham, Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: In December, 2020, Congress passed the Consolidated Appropriations Act, 2021 (CAA, 2021). Section 407 of CAA, 2021, amended Part A of Title XVIII of the Social Security Act (the Act) at section 1822 establishing hospice program

survey and enforcement requirements. This amendment, in part, now requires the Accrediting Organizations (AOs) that accredit hospice programs to include the form CMS-2567 to document the findings of their hospice program surveys beginning on October 1, 2021. Public harm is reasonably likely to ensue if the normal, non-emergency clearance procedures are followed. CMS would miss the statutorily mandated deadline of October 1, 2021 for Accrediting Organizations (AOs), with a hospice program, to begin using the form CMS-2567. AOs will not have the revised form to include in their current survey documentation systems and processes and will not meet the deadline of October 1, 2021 for beginning use. If CMS misses the deadline, it will jeopardize another CAA, 2021 mandated provision deadline for public posting of these AO hospice program survey reports on our website. The purpose of this requirement is for public transparency of survey and certification information. This statutory provision requires that the hospice program survey reports be posted by no later than October 1, 2022. Additionally, the public may not have all the information necessary to make an informed decision regarding where they seek high quality, safe care hospice program organizations for themselves or loved ones. Beneficiaries and the public at large utilize survey findings when evaluating whether to receive care from certain facilities.

Under the PRA, federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS-2567 Statement of Deficiency and Plan of Correction

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management

and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public: Submit reports, keep records, or provide information to a third party. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

Information Collection

1. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Statement of Deficiency and Plan of Correction **Use:** The form CMS-2567 is the means by which State and CMS surveyors document findings of compliance or noncompliance (deficiencies) resulting from inspection of Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) laboratories. The form CMS-2567 is the legal, documentary basis for CMS' certification of a facility's compliance or noncompliance with the Medicare/Medicaid Conditions of Participation or Coverage, and the requirements for Nursing Home participation and CLIA certification.

In December, 2020, Congress passed the Consolidated Appropriations Act, 2021 (CAA, 2021). Section 407 of CAA, 2021, amended Part A of Title XVIII of the Social Security Act (the Act) at section 1822 establishing hospice program survey and enforcement requirements. This amendment, in part, now requires the Accrediting Organizations (AOs) that accredit hospice programs to include the form CMS-2567 to document the findings of their hospice program surveys beginning on October 1, 2021. As of June 2021, there are three AOs with CMS-approved hospice accreditation programs. The AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half.

To enable AOs to use the form CMS-2567, we must revise it by adding fields for the AO name. Also, the instructions must be updated to include AOs as another group which utilizes the form CMS-2567. We have also included the burden calculations from CMS-1747-P (*Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update*), related to the one-time update needed to each of AO's proprietary electronic systems in order to use the form CMS-2567 as directed by the CAA, 2021. **Form Numbers:**

CMS-2567 (OMB control number: 0938-0391); **Frequency:** Yearly and Occasionally; **Affected Public:** Private Sector (Business or for-profits and Not-for-profit institutions); **Number of Respondents:** 65,948; **Total Annual Responses:** 65,948; **Total Annual Hours:** 1,210,376. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

Dated: July 8, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021-14866 Filed 7-12-21; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen—dsat), manufactured by Stratatech, a Mallinckrodt Company, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the

Cures Act (Pub. L. 114-255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen—dsat), manufactured by Stratatech, a Mallinckrodt Company, meets the criteria for a material threat MCM priority review voucher. STRATAGRAFT is indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation>. For further information about STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen—dsat), go to the Center for Biologics Evaluation and Research Approved Cellular and Gene Therapy Products website at <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.

Dated: July 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-14779 Filed 7-12-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1048]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with medical device labeling regulations.

DATES: Submit either electronic or written comments on the collection of information by September 13, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 13, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-1048 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Labeling Regulations

OMB Control No. 0910-0485—Revision

This information collection supports implementation of medical device labeling requirements governed by section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), codified in Agency regulations, and discussed in associated Agency guidance. Medical device labeling requirements, among other things, provide for the label or labeling content of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions under section 502 of the FD&C Act require that

manufacturers, importers, and distributors of medical devices disclose information about themselves or the devices on the labels or labeling for the devices. Section 502 provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use. Medical device labeling regulations in parts 800, 801, 809, and associated regulations in part 1040 (21 CFR parts 800, 801, 809, and 1040), prescribe the disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves and/or the devices, on the label or labeling for the devices, to health professionals and consumers.

In conjunction with provisions in part 800, part 801, subpart A sets forth general labeling provisions applicable to all medical devices, including content and format requirements pertaining to intended uses, adequate directions for use, misleading statements, and the prominence of required labeling. Information collection provisions found in part 801, subpart B pertaining to labeling requirements for Unique Device Identification are currently approved under OMB control number 0910–0720 and not covered in this information collection request. Information collection associated with labeling requirements for Over-the-Counter (OTC) Devices are found in part 801, subpart C, and cover principal display panel; statement of identity; declaration of net quantity of contents; and certain warning statement elements. Information collection associated with exemptions from adequate directions for use and other exemptions are found in part 801, subparts D and E, respectively. Information collection associated with special labeling requirements applicable

to specific devices are found in part 801, subpart H. We also include information collection associated with labeling for in vitro diagnostic products for human use, as set forth in part 809, subpart B. Finally, in addition to the labeling requirements in part 801 and the certification and identification requirements of 21 CFR 1010.2 and 1010.3, sunlamp products and ultraviolet lamps are subject to specific labeling requirements as set forth in part 1040.

We have revised the information collection to include reference to Agency guidance. The guidance documents were developed and issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Section 502(b) of the FD&C Act requires that, for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may, however, grant an exemption if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case as it relates to protection of the public health. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250) amended section 502 of the FD&C Act to add paragraph (u) to section 502 to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (MDUFSA) amended section 502(u) of

the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. MDUFSA required that FDA issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not “prominent and conspicuous” under section 502(u) of the FD&C Act. Accordingly, we issued the guidance document entitled “Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices” (May 2006), available at <https://www.fda.gov/media/71187/download>. The guidance document is intended to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act. We believe the information disclosures discussed in the guidance impose no burden beyond that which we attribute already to complying with disclosure provisions found in the applicable regulations; however, we include the guidance document for respondents’ instructional use and reference.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Symbols glossary	3,000	1	3,000	1	3,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our figures are based on data from the FDA Unified Registration and Listing System and the OASIS shipment information. FDA allows the use of stand-alone graphical representations of

information, or symbols, in the labeling for the medical devices, if the symbol has been established in a Standards Development Organization developed standard, provided that such symbol is

explained in a symbols glossary that is included in the labeling for the medical device and otherwise complies with section 502 (misbranding) of the FD&C Act.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Processing, labeling, or repacking agreement; 801.150.	7,500	887	6,652,500	0.5 (30 minutes)	3,326,250
Impact resistant lenses; invoices, shipping documents, and records of sale or distribution; 801.410(e) and (f).	1,591	47,050	74,856,550	0.0008 (0.048 minutes)	59,885
Hearing aid records; 801.421	10,000	160	1,600,000	0.25 (15 minutes)	400,000
Menstrual tampons, sampling plan for measuring absorbency; 801.430(f).	33	11	363	80	29,040
Latex condoms; justification for the application of testing data to the variation of the tested product; 801.435(g).	51	3.65	186	1	186
Total			83,109,599		3,815,361

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded.

As set forth in § 801.150(a)(2) (21 CFR 801.150(a)(2)), device manufacturers are required to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the final shipment or delivery of the device. Section 801.150(a)(2) requires that copies of this agreement be made available for inspection at any reasonable hour upon request by any

officer or employee of the Department of Health and Human Services (HHS). In § 801.410(e) (21 CFR 801.410(e)) copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, are required to be maintained for 3 years by the retailer and made available upon request by any officer or employee of FDA or by any other officer or employee

acting on behalf of the Secretary of HHS. Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years. Specific recordkeeping requirements applicable to hearing aid dispensers, manufacturers of menstrual tampons, and manufacturers of latex condoms are set forth in 21 CFR 801.421(d), 801.430(f), and 801.435(g), respectively.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN^{1 2}

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Parts 800; and Part 801, subparts A, C, D, and E: General Labeling; OTC Devices; Exemptions					
Contact lens cleaning solution labeling; 800.10(a)(3) and 800.12(c).	47	8	376	1	376
Liquid ophthalmic preparation labeling; 800.10(b)(2)	25	8	200	1	200
Manufacturer, packer, or distributor information; 801.1	19,407	7	135,849	1	135,849
Adequate directions for use; 801.5	8,526	6	51,156	22.35	1,143,337
Statement of identity; 801.61	8,526	6	51,156	1	51,156
Declaration of net quantity of contents; 801.62	8,526	6	51,156	1	51,156
Prescription device labeling; 801.109	9,681	6	58,086	17.77	1,032,188
Retail exemption for prescription devices; 801.110	30,000	667	20,010,000	0.25	5,002,500
Processing, labeling, or repacking; non-sterile devices; 801.150(e).	453	34	15,402	4	61,608
Part 801, subpart H: Special Requirements for Specific Devices					
Labeling of articles intended for lay use in the repairing and/or refitting of dentures; 801.405(b)(1).	35	1	35	4	140
Dentures; information regarding temporary and emergency use; 801.405(c).	35	1	35	4	140
Hearing aids professional and patient labeling; 801.420	136	12	1,632	80	130,560
Hearing aids, availability of User Instructional Brochure; 801.421.	10,000	5	50,000	0.17	8,500
User labeling for menstrual tampons; 801.430	16	8	128	2	256
User labeling for latex condoms; 801.437	52	6	312	100	31,200
Part 809 (in vitro diagnostic products for human use) and Part 1040 (light-emitting products)					
Format and content of labeling for IVDs; 809.10	1,700	6	10,200	80	816,000
Advertising and promotional materials for ASRs; 809.30(d)	300	25	7,500	1	7,500
Labeling of sunlamp products—1040.20(d)	30	1	30	10	300

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ^{1 2}—Continued

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
FD&C Action Section 502(u)					
Establishments listing <10 SUDs	161	2	322	0.1 (6 minutes)	32
Establishments listing >10 SUDs	14	45	630	0.1 (6 minutes)	63
Total			952		95

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded.

Because many labeling provisions correspond to specific recordkeeping requirements, we have accounted for burden attendant to the provisions enumerated in table 3 as third-party disclosures. These figures reflect what we believe to be the average burden incurred by respondents to applicable information collection activities.

Overall, the information collection reflects changes and adjustments. For efficiency of operations, we have consolidated related information collection currently approved under OMB control numbers 0910–0577 and 0910–0740 pertaining to recommendations found in Agency guidance and discussed in this notice. This results in an increase to the information collection by 30,482 burden hours annually. At the same time, we have reduced our estimate of the total responses by 53,143,810 annually. Upon review, we believe we previously double-counted burden ascribed to disclosures provisions having accounted for the same burden as that associated with recordkeeping activities. We invite comment on our estimates and these assumptions.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14768 Filed 7–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Advanced Nursing Education Program Specific Form OMB No. 0915–0375—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR. **DATES:** Comments on this ICR should be received no later than September 13, 2021.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Advanced Nursing Education (ANE)

Program Specific Form OMB No. 0915–0375—Revision.

Abstract: HRSA provides advanced nursing education grants to educational institutions to increase the supply, distribution, quality of, and access to advanced education nurses through the ANE Programs. The ANE Programs are authorized by Section 811 of the Public Health Service Act (42 U.S.C. 296j), as amended. This clearance request is for continued approval of the information collection OMB No. 0915–0375 with revisions.

This revision request includes a title change from the Advanced Nursing Education Workforce (ANEW) Program-Specific Data Collection Forms to ANE Program Specific Form. This revision also merges forms used by the ANEW Program and adds several other new forms from the ANE Programs, including the Advanced Nursing Education Nurse Practitioner Residency (ANE–NPR) Program, Advanced Nursing Education Nurse Practitioner Residency Integration Program (ANE–NPRIP), Nurse Anesthetist Traineeship (NAT) Program, and Advanced Nursing Education Sexual Assault Nurse Examiners (ANE–SANE) Program. The revision of the ANE Program Specific Form incorporates elements from these four programs (ANE–NPR, ANE–NPRIP, NAT, and ANE–SANE) into the ANE Program Specific Form.

Need and Proposed Use of the Information: Section 811 of the Public Health Service Act provides the Secretary of HHS with the authority to award grants to and enter into contracts with eligible entities to meet the costs of—(1) projects that support the enhancement of advanced nursing education and practice; and (2) traineeships for individuals in advanced nursing education programs. Under this section, HRSA makes awards to entities who train and support nurses characterized as “advanced education nurses.” In awarding such grants, funding preference is given to applicants with projects that will

substantially benefit rural or underserved populations, or help meet public health nursing needs in state or local health departments; special consideration is given to an eligible entity that agrees to extend the award to train advanced education nurses who will practice in designated health professional shortage areas.

The ANE Program Specific Form will allow HRSA to effectively target funding and measure the impact of the ANE programs in meeting the legislative intent and program goals of supporting the enhancement of advanced nursing education and creating opportunities for individuals in advanced nursing education programs to increase the number of advanced practice nurses, especially in rural and underserved areas. The proposed updates to this information collection will assist HRSA in: streamlining the application submission process across programs; enabling an efficient award determination process; and facilitating HRSA's ability to monitor the use of funds and analyze program outcomes. Additionally, collecting this data assists HRSA in carrying out the most impactful program and ensuring resources are used responsibly.

More specifically, the changes include the following:

- Form name change from ANEW to ANE Program Specific Form.

- Additional instructions for applicants are provided in each funding opportunity.

- Modifications to both Table #1 and Table #2:

- Revision to instructions to incorporate elements for added programs. Instructions about completion of each table are included within the electronic application materials.
- Table titles are rephrased for clarity.

- New "Additional Specialty" column is created to yield a flexible data collection option.

- Table #1 rows are numbered for clarity and more rows are added to:
 - Capture auto-tabulation, and
 - Reformat/separate Statutory Funding Preference data from Special Consideration data.

- Table #2 has:

- "Students" reworded to "participants/trainees";

- One column labeled, "Budget Year," to identify the project budget year;

- One column to create a space for entering the sum for each row;

- Rows to more clearly indicate the budget year for up to five years; and,

- One final row to create a space for entering the total for each column.

- Frequency of data collection: Data is collected (through the two tables)

once during the application period for each funding announcement.

- Information determines:

- If applicants meet the funding preference or special consideration for funding; and

- Projected target and baseline numbers of trainees/participants to be supported throughout the project period.

Likely Respondents: Likely respondents will be current ANE Programs awardees and new applicants to the ANE Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name (includes the ANE program specific tables and attachments)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
ANEW	236	1	236	7	1,652
NAT	115	1	115	7	805
ANE-NPR	101	1	101	7	707
ANE-NPRIP	15	1	15	7	105
ANE-SANE	54	1	54	7	378
Total	521		521		3,647

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021-14804 Filed 7-12-21; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and

development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential

Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Mononegavirales Vectors Expressing Chimeric Antigens

Description of Technology

Human respiratory syncytial virus (RSV) continues to be the leading viral cause of severe acute lower respiratory tract disease in infants and children worldwide, and also is an important cause of morbidity and mortality in the elderly. A licensed vaccine or antiviral drug suitable for routine use remains unavailable. This invention relates to the use of murine pneumonia virus (MPV—previously known as pneumonia virus of mice, PVM—of family *Pneumoviridae*) as a vaccine vector expressing the RSV fusion protein F, the most important protective antigen of RSV. MPV is not a human pathogen and is not restricted by immunity to common human viruses. MPV replicates in the superficial epithelial cells of the respiratory mucosa and is expected to be attenuated in humans based on the strong host range restriction observed in non-human primates. To generate these MPV/RSV vector vaccine candidates, the RSV F ORF was codon optimized, placed under the control of MPV transcription signals, and inserted at the first (rMPV-F1), third (rMPV29 F3), or fourth (rMPV-F4) gene position of a version of the MPV genome that contained a codon-pair optimized L polymerase gene. The recovered viruses replicated *in vitro* as efficiently as the empty vector, with stable expression of RSV F protein. Replication and immunogenicity of rMPV-F1 and rMPV-F3 were evaluated in rhesus macaques following administration by the combined intranasal and intratracheal routes. Both viruses replicated at low levels in the upper and lower respiratory tract, maintained stable RSV F expression, and induced similarly high levels of RSV-neutralizing serum antibodies that reached peak titers by fourteen (14) days post-vaccination. Thus, rMPV provides a highly attenuated yet immunogenic vector for the expression of RSV F protein, with potential application in RSV-naïve and RSV-experienced populations. RSV F was expressed in the wild-type form, but can readily be engineered to be stabilized in the highly immunogenic prefusion form, as has been done with parainfluenza virus vectors.

The invention relates to live, chimeric non-human *Mononegavirales* vectors

that allow a cell to express at least one protein from at least one human pathogen as well as compositions comprising the vectors, methods and kits for eliciting an immune response in a host, and methods of making the vectors.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Viral diagnostics
- Vaccine research

Competitive Advantages

- Ease of manufacture
- Multivalent live attenuated vaccines
- B cell and T cell activation
- Low-cost vaccines

Development Stage

- In vivo data assessment (animal)
- Inventors:* Shirin Munir (NIAID), Linda Brock (NIAID), Ursula Buchholz (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-018-2018/0—U.S. Provisional Application No. 62/661,320, filed April 23, 2018 (expired), PCT Patent Application No. PCT/US2019/028771, filed April 23, 2019 (expired), Taiwanese Patent Application No. 108114132, filed April 23, 2019 (pending), Brazilian Patent Application No. BR112020021652-6, filed October 22, 2020 (pending), Australian Patent Application No. 2019261570, filed October 21, 2020 (pending), Canadian Patent Application No. 3097888, filed October 20, 2020 (pending), Chinese Patent Application No. 201980039372.6, filed December 15, 2020 (pending), European Patent Application No. 19729386.3, filed November 13, 2020 (pending), Indian Patent Application No. 20204706248, filed October 23, 2020, Japanese Patent Application No. 2020-558967, filed October 22, 2020, South Korean Patent Application No. 2020-7033157, filed November 18, 2020, and United States Patent Application No. 17/049,916, filed October 22, 2020.

Licensing Contact: Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter

Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

Dated: July 8, 2021.

Anna V. Ganelina,

Senior Technology Transfer and Patenting Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-14820 Filed 7-12-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: TSA Customer Comment Tools

AGENCY: Transportation Security Administration, Homeland Security (DHS).

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0030, abstracted below to OMB for a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. This collection allows customers to provide feedback to TSA about their experiences with TSA's processes and procedures, to request information or request assistance at the TSA checkpoint, and to report security threats and vulnerabilities.

DATES: Send your comments by August 12, 2021. A comment to OMB is most effective 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 Review—Open for Public Comments" or by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA-11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598-6011; telephone (571) 227-2062; email TSAPRA@dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice,

with a 60-day comment period soliciting comments, of the following collection of information on April 13, 2021 (86 FR 19276).

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be made available at <http://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: TSA Customer Comment Tools.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652-0030.

Forms(s): NA.

Affected Public: Travelling public.

Abstract: The TSA Contact Center (TCC) continues to serve as the main portal of communication for the traveling public. The public may contact the TCC via email or phone to request information, file a complaint—general or Civil Rights and Liberties, compliment, or provide general feedback. With over one million contacts per year, it is crucial for TSA to have the ability to capture this information. TSA's online submission forms are readily available from the Customer Service portion of tsa.gov. The online forms are easy to use and offer several dropdown menu choices to reduce the burden on the public and increase the quality of data for TSA. Currently, there are four options for the online forms: Complaint and Compliment, Request for Assistance, Request for Information, and Security Issues. The online forms are easy to use and offer several dropdown menu choices to reduce the burden on the

public and increase the quality of data for TSA. TCC provides a receipt to any person who submits an online form.

TSA is revising the information collection, moving from four online forms to six electronic forms. The online form Complaint and Compliment has been broken into two separate distinct online forms. TSA PreCheck™ has been pulled out of the drop down menu of Complaint and given its own online form. Request for Assistance online form has been renamed TSA Cares. The 6 online forms are as follows:

- *Complaint*—passengers may provide a complaint regarding their experiences with TSA security procedures. Passengers may also use this form to file Disability or Civil Rights and Civil Liberties complaints.

- *TSA PreCheck*—passengers may share concerns about not receiving TSA PreCheck on their boarding pass or other concerns.

- *Compliment*—passengers may share how TSA exceeded their expectations.

- *Request for Information*—passengers may submit an inquiry about TSA policies and procedures, such as traveling with medical conditions, prohibited & permitted items, security screening and more.

- *TSA Cares*—passengers may request assistance through the TSA screening checkpoint.

- *Security Issue*—passengers may identify and report suspicious activities and threats. The TCC provides a receipt to any person who submits an electronic form or email to TSA as required by 49 CFR 1503.3(a).

Also, TSA is changing the name of OMB control number 1652-0030 from “TSA Customer Comment Card” to “TSA Customer Comment Tools” to more accurately represent the information collection. In addition, TSA is making non-substantive changes to the paper comment card, updating the appearance—font, TSA insignia and spacing.

Number of Respondents: An estimated 88,352 respondents annually.

Estimated Annual Burden Hours: An estimated 7,518 hours annually.

Christina A. Walsh,

*TSA Paperwork Reduction Act Officer,
Information Technology.*

[FR Doc. 2021-14886 Filed 7-12-21; 8:45 am]

BILLING CODE 9110-05-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-HQ-MB-2021-N170; FF09M13200/201/FXMB1233090000; OMB Control Number 1018-0172]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Federal Migratory Bird Hunting and Conservation Stamp (Duck Stamp) and Junior Duck Stamp Contests

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), 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 August 12, 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 clicking on the link “Currently under Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB/PERMA (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041-3803 (mail); or by email to Info_Coll@fws.gov. Please reference OMB Control Number 1018-0172 in the subject line of your comments.

FOR FURTHER INFORMATION 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. You may also view the information collection request (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.

On March 4, 2021, we published in the **Federal Register** (86 FR 12707) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on May 3, 2021. We received one comment in response to that notice, expressing concern that the programs were morally wrong because they supported wildlife hunting. The comment did not address the information collection requirements, so no response is required.

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

History of the Federal Duck Stamp

On March 16, 1934, Congress passed, and President Franklin D. Roosevelt

signed, the Migratory Bird Hunting Stamp Act (16 U.S.C. 718–718k). Popularly known as the Duck Stamp Act, it required all waterfowl hunters 16 years or older to buy a stamp annually. The revenue generated was originally earmarked for the Department of Agriculture, but 5 years later was transferred to the Department of the Interior and the Service.

In the years since its enactment, the Federal Duck Stamp Program has become one of the most popular and successful conservation programs ever initiated. Today, some 1.5 million stamps are sold each year, and as of 2017, Federal Duck Stamps had generated more than \$1 billion for the preservation of more than 6 million acres of waterfowl habitat in the United States. Numerous other birds, mammals, fish, reptiles, and amphibians have similarly prospered because of habitat protection made possible by the program. An estimated one-third of the Nation's endangered and threatened species find food or shelter in refuges preserved by Duck Stamp funds. Moreover, the protected wetlands help dissipate storms, purify water supplies, store flood water, and nourish fish hatchlings important for sport and commercial fishermen.

History of the Duck Stamp Contest

Jay N. “Ding” Darling, a nationally known political cartoonist for the *Des Moines Register* and a noted hunter and wildlife conservationist, designed the first Federal Duck Stamp at President Roosevelt's request. In subsequent years, noted wildlife artists submitted designs. The first Federal Duck Stamp Contest was opened in 1949 to any U.S. artist who wished to enter, and 65 artists submitted a total of 88 design entries. Since then, the contest has been known as the Federal Migratory Bird Hunting and Conservation Stamp Art (Duck Stamp) Contest and has attracted large numbers of entrants.

The Duck Stamp Contest (50 CFR part 91) remains the only art competition of its kind regulated by the U.S. Government. The Secretary of the Interior appoints a panel of noted art, waterfowl, and philatelic authorities to select each year's winning design. Winners receive no compensation for the work, except a signed pane of their stamps; however, winners retain the copyright to their artwork and may sell the original and prints of their designs, which are sought by hunters, conservationists, and art collectors.

For the Duck Stamp Contest, the Service selects five or fewer species of waterfowl each year; each entry must employ one of the Service-designated

species as the dominant feature (defined as being in the foreground and clearly the focus of attention). In 2020 a permanent theme was established, and participants are currently also required to include a mandatory waterfowl hunting accessory or waterfowl hunting scene within their design. These may include objects such as hunting dogs, waterfowl decoys, waterfowl hunters and scenes illustrating the theme “celebrating our waterfowl hunting heritage.” Designs may also include national wildlife refuges as the background of habitat scenes, non-eligible species, or other scenes that depict uses of the stamp for conservation and collecting purposes. Entries may be in any media, except for photography or computer-generated art. Designs must be the contestants' original hand-drawn creation and may not be copied or duplicated from previously published art, including photographs, or from images in any format published on the internet.

History of the Junior Duck Stamp Contest

The Federal Junior Duck Stamp Conservation and Design Program (Junior Duck Stamp Program) began in 1989 as an extension of the Migratory Bird Conservation and Hunting Stamp. The national Junior Duck Stamp art contest started in 1993, and the first stamp design was selected from entries from eight participating States. The program was recognized by Congress with the 1994 enactment of the Junior Duck Stamp Conservation and Design Program Act (16 U.S.C. 719). All 50 States, Washington DC, and 2 of the U.S. Territories currently participate in the annual contest.

The Junior Duck Stamp Program introduces wetland and waterfowl conservation to students in kindergarten through high school. It crosses cultural, ethnic, social, and geographic boundaries to teach greater awareness and guide students in exploring our nation's natural resources. It is the Service's premier conservation education initiative.

The Junior Duck Stamp Program includes a dynamic art-and-science-based curriculum. This nontraditional pairing of subjects brings new interest to both the sciences and the arts. The program teaches students across the nation conservation through the arts, using scientific and wildlife observation principles to encourage visual communication about what they learn. Four curriculum guides, with activities and resources, were developed for use as a year-round study plan to assist

students in exploring science in real-life situations.

Modeled after the Federal Duck Stamp Contest, the annual Junior Duck Stamp Art and Conservation Message Contest (Junior Duck Stamp Contest) was developed as a visual assessment of a student's learning and progression. The Junior Duck Stamp Contest encourages partnerships among Federal and State government agencies, nongovernmental organizations, businesses, and volunteers to help recognize and honor thousands of teachers and students throughout the United States for their participation in conservation-related activities. Since 2000, the contest has received more than 530,000 entries.

The winning artwork from the national art contest serves as the design for the Junior Duck Stamp, which the Service produces annually. This \$5 stamp has become a much sought after collector's item. One hundred percent of the revenue from the sale of Junior Duck stamps goes to support recognition and environmental education activities for students who participate in the program. More than \$1.25 million in Junior Duck Stamp proceeds have been used to provide recognition, incentives, and scholarships to participating students, teachers, and schools. The Program continues to educate youth about land stewardship and the importance of connecting to the natural world. Several students who have participated in the Junior Duck Stamp Program have gone on to become full-time wildlife artists and conservation professionals; many attribute their interest and success to their early exposure to the Junior Duck Stamp Program.

Who Can Enter the Federal Duck Stamp and Junior Duck Stamp Contests

The Duck Stamp Contest is open to all U.S. citizens, nationals, and resident

aliens who are at least 18 years of age by June 1. Individuals enrolled in kindergarten through grade 12 may participate in the Junior Duck Stamp Contest. All eligible students are encouraged to participate in the Junior Duck Stamp Conservation and Design Program annual art and conservation message contest as part of the program curriculum through public, private, and homeschools, as well as through nonformal educational experiences such as those found in scouting, art studios, and nature centers.

Entry Requirements

Each entry in the Duck Stamp Contest requires a completed entry form and an entry fee. Information required on the entry form includes:

- "Display, Participation & Reproduction Rights Agreement" certification form;
- Basic contact information (name, address, phone numbers, and email address);
- Date of birth (to verify eligibility);
- Species portrayed and medium used; and
- Name of hometown newspaper (for press coverage).

Each entry in the Junior Duck Stamp Contest requires a completed entry form that requests:

- Basic contact information (name, address, phone numbers, and email address);
- Age/grade (to verify eligibility and so they may be judged with their peers);
- Parent's name and contact information (email address and phone numbers);
- Whether the student has a Social Security or VISA immigration number or is a foreign exchange student (to verify eligibility to receive prizes);
- Title, species, medium/style used, and conservation message associated with the drawing;

- Basic contact information for their teacher and school (name, address, phone numbers, school/studio/organization/troop name, and email address); and

- Certification of authenticity.

Students in grades 7 through 12 and all national level students are also required to include citations for any resources they used to develop their designs. We use this information to verify that the student has not plagiarized or copied someone else's work. The Service also translates entry forms into other appropriate languages to increase the understanding of the rules and what the parents and students are signing.

Title of Collection: Federal Migratory Bird Hunting and Conservation Stamp (Duck Stamp) and Junior Duck Stamp Contests.

OMB Control Number: 1018-0172.

Form Number: None.

Type of Review: Revision of a currently approved information collection.

Respondents/Affected Public: Individuals.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: \$53,000 annually (entry fees of \$125 plus an average of \$15 for mailing costs, for an estimated 200 annual submissions to the Federal Duck Stamp Contest). There are no fees associated with the Junior Duck Stamp Contest submissions. We estimate the mailing costs associated with entering submissions to the Junior Duck Stamp contest to be approximately \$25,000 annually. Most of the student entries are mailed directly by schools, who utilize the bulk mail option, thereby reducing the amount of postage and packages received.

Activity	Total number of annual respondents	Average number of submissions each	Total number of annual responses	Average completion time per response (min)	Total annual burden hours *
Duck Stamp Program Contest Entry Form Individuals	200	1	200	7	23
Junior Duck Stamp Program Contest Entry Form Individuals	25,000	1	25,000	** 20	8,333
Totals	25,200	1	25,200		8,356

* Rounded.

** Burden for Junior Duck Stamp Program entry form is longer since both the parents and teacher must sign the form, and the student must provide references.

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. 2021-14847 Filed 7-12-21; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-HQ-NWRS-2021-N162;
FXRS12630900000-201-FF09R81000; OMB
Control Number 1018-0102]

Agency Information Collection Activities; National Wildlife Refuge Special Use Permit Applications and Reports

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, we), are proposing to revise an existing collection of information.

DATES: Interested persons are invited to submit comments on or before September 13, 2021.

ADDRESSES: Send your comments on the information collection request by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041-3803 (mail); or by email to Info_Coll@fws.gov. Please reference OMB Control Number 1018-0102 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.

SUPPLEMENTARY INFORMATION: In accordance with the PRA 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.

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. 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 National Wildlife Refuge System Administration Act of 1966 (Administration Act; 16 U.S.C. 668dd-668ee), as amended by the National Wildlife Refuge System Improvement Act of 1997, consolidated all refuge units into a single National Wildlife Refuge System (system). It also authorized us to offer visitor and public programs, including those facilitated by commercial visitor and management support services, on lands of the system when we find that the activities are appropriate and compatible with the purpose(s) for which the refuge was established and the system's mission. The Refuge Recreation Act of 1962 (Recreation Act; 16 U.S.C. 460k-460k-4) allows the use of refuges for public recreation when it is not inconsistent or does not interfere with the primary purpose(s) of the refuge. The Alaska National Interest Lands Conservation Act (ANILCA; 16 U.S.C. 3101 *et seq.*) provides specific authorization and

guidance for the administration and management of national wildlife refuges within the State of Alaska. Its provisions provide for the issuance of permits under certain circumstances.

We issue special use permits for a specific period as determined by the type and location of the management activity or visitor service provided. These permits authorize activities such as:

- Agricultural activities (haymaking and grazing, 50 CFR 29.1 and 29.2).
- Beneficial management tools that we use to provide the best habitat possible on some refuges (50 CFR 30.11, 31.14, 31.16, and 36.41).
- Special events, group visits, and other one-time events (50 CFR 25.41, 25.61, 26.36, and 36.41).
- Recreational visitor service operations (50 CFR 25.41, 25.61, and 36.41).
- Guiding for fishing, hunting, wildlife education, and interpretation (50 CFR 25.41 and 36.41).
- Commercial filming (43 CFR 5, 50 CFR 27.71) and other commercial activities (50 CFR 29.1 and 36.41).
- Building and using cabins to support subsistence or commercial activities (in Alaska) (50 CFR 26.35 and 36.41).
- Research, inventory and monitoring, and other noncommercial activities (50 CFR 26.36 and 36.41).

We use three forms to collect applicant information:

- FWS Form 3-1383-G (General Activities Special Use Application).
- FWS Form 3-1383-C (Commercial Activities Special Use Application).
- FWS Form 3-1383-R (Research and Monitoring Special Use Application).

The information we collect helps ensure that: (1) Applicants are aware of the types of information that may be needed for permit issuance; (2) requested activities are appropriate and compatible with the purpose(s) for which the refuge was established and the system's mission; and (3) the applicant is eligible or is the most qualified applicant to receive the special use permit.

We may collect the necessary information in a non-form format (through discussions in person or over the phone, over the internet, by email, or by letter). In some instances, respondents will be able to provide information verbally. Often, a simple email or letter describing the activity will suffice. For activities that might have a large impact on refuge resources (*e.g.*, commercial visitor services, research, etc.), we may require applicants to provide more detail on operations, techniques, and locations.

Because of the span of activities covered by special use permits and the different management needs and resources at each refuge, respondents may not be required to answer all questions. Depending on the requested activity, refuge managers have the discretion to ask for less information than appears on the forms. However, refuge managers must not ask for more or different information.

We issue permits for a specific period as determined by the type and location of the use or service provided. We use these permits to ensure that the applicant is aware of the requirements of the permit and his/her legal rights. Refuge-specific special conditions may be required for the permit. We identify conditions as an addendum to the permit. Most of the special conditions pertain to how a permitted activity may be conducted and do not require the collection of information. However, some special conditions, such as activity reports, before and after site photographs, or data sharing, would qualify as an information collection, and we have included the associated burden below.

We also use FWS Form 3–1384, “Bid Sheet—National Wildlife Refuge System” to streamline collection of the necessary pre-award information from applicants during bidding processes to conduct economic uses on Service lands, such as livestock, harvesting hay and stock feed, or removing timber (50 CFR 29.21). This form simplifies the pre-award selection/bidding process for bidders and for refuge staff by enabling them to understand what information the refuge needs in order to select bids for economic use, and, therefore, reduces the time and burden for the public and Service staff in the pre-award selection bidding process. This form is customizable to the individual economic use being awarded. We will use the Commercial Special Use Permit (FWS Form 3–1383–C) as the actual award document that will outline the terms and conditions of the economic use on Service lands.

Proposed Revisions to This Information Collection

With this submission, we are proposing the following revisions to the existing information collection:

Activity Reports/Associated Document Requirements

In addition to the previously approved activity report criteria, the Service will also collect data associated with client use days and their fees. The Service has also updated the reporting rate for permits issued for both Commercial Use and Research to reflect current requirements.

ePermits Initiative

The Service’s new “ePermits” initiative is an automated permit application system that will allow the agency to move towards a streamlined 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 intent of the ePermits initiative is to fully automate the permitting process to improve the customer experience and to reduce time burden on respondents. This new system will enhance the user experience by allowing users to enter data from any device that has internet access, including PCs, tablets, and smartphones. It will also link the permit applicant to the *Pay.gov* system for payment of the associated permit application fee. We anticipate including the following Service forms in the ePermits system: 3–1383–G, 3–1383–C, 3–1383–R, and 3–1384.

Once these forms are automated in the new ePermits system, we anticipate a reduction in the amount of time necessary for an applicant to apply for a permit and perform regular actions related to that permit (e.g., amend, renew, report). Through the ePermits account registration, we will track and be able to more accurately report the number of small business applicants, along with the type of business (for-profit, farm, not-for profit). This information will allow the Service to be more responsive in identifying the possibility of additional burden reduction on small businesses.

We also plan to eliminate the necessity for physical mail-in applications (though this will remain an option for those who either don’t have access to the internet or prefer to use mail-in applications), thus further

reducing public burden. With ePermits, an applicant will be able to establish an account and apply for multiple permits through a single interface. The system allows the applicant to track all their applications, permits and permit-related actions, as well as all communications between Service staff and the permittee/applicant within the same interface, significantly reducing the burden on the government to process these applications and manage permit-related actions. The decrease in submissions of paper-based forms is expected to reduce the government cost of administering and processing permit applications.

Amendments and Renewals

Through our review of the special use permitting process in preparation for automation in the ePermits system, we discovered that we need to account for amendments to and renewals of special use permits separately from the initial applications, because amendments/renewals have time burdens that are different from those of the initial submissions. The revised burden table below includes our initial estimates for amendments and renewals.

Title of Collection: National Wildlife Refuge Special Use Permit Applications and Reports, 50 CFR 25, 26, 27, 29, 30, 31, 32, & 36.

OMB Control Number: 1018–0102.

Form Number: FWS Forms 3–1383–G, 3–1383–C, 3–1383–R, and 3–1384.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individuals and households; businesses and other for-profit organizations; nonprofit organizations; farms; and State, local, or tribal governments.

Respondent’s Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for applications; annually or on occasion for reports.

Total Estimated Annual Nonhour Burden Cost: \$259,500 for fees associated with applications for commercial use activities (\$100.00 × an estimated 2,595 applications (individuals and private sector respondents only)).

Requirement	Annual number of respondents	Total annual responses	Completion time per response (hours)	Total annual burden hours*
General Special Use Application (Form 3–1383–G):				
Individuals	1,142	1,142	0.5	571
Private Sector	609	609	0.5	305
Government	152	152	0.5	76

Requirement	Annual number of respondents	Total annual responses	Completion time per response (hours)	Total annual burden hours*
<i>ePermits</i> —General Special Use Application (Form 3–1383–G):				
Individuals	1,143	1,143	0.33	377
Private Sector	610	610	0.33	201
Government	153	153	0.33	50
Amendments—General Special Use Application (Form 3–1383–G):				
Individuals	114	114	0.25	29
Private Sector	61	61	0.25	15
Government	15	15	0.25	4
<i>ePermits Amendments</i> —General Special Use Application (Form 3–1383–G):				
Individuals	114	114	.2	23
Private Sector	61	61	.2	12
Government	15	15	.2	3
Renewals—General Special Use Application (Form 3–1383–G):				
Individuals	228	228	.33	75
Private Sector	122	122	.33	40
Government	30	30	.33	10
<i>ePermits Renewals</i> —General Special Use Application (Form 3–1383–G):				
Individuals	228	228	.25	57
Private Sector	122	122	.25	31
Government	30	30	.25	8
Commercial Activities Special Use Application (Form 3–1383–C):				
Individuals	797	797	4	3,188
Private Sector	500	500	4	2,000
Government	54	54	4	216
<i>ePermits</i> —Commercial Activities Special Use Application (Form 3–1383–C):				
Individuals	798	798	3.75	2,993
Private Sector	500	500	3.75	1,875
Government	54	54	3.75	203
Amendments—Commercial Activities Special Use Application (Form 3–1383–C):				
Individuals	80	80	1	80
Private Sector	50	50	1	50
Government	5	5	1	5
<i>ePermits Amendments</i> —Commercial Activities Special Use Application (Form 3–1383–C):				
Individuals	80	80	0.75	60
Private Sector	50	50	0.75	38
Government	5	5	0.75	4
Renewals—Commercial Activities Special Use Application (Form 3–1383–C):				
Individuals	160	160	2	320
Private Sector	100	100	2	200
Government	27	27	2	54
<i>ePermits Renewals</i> —Commercial Activities Special Use Application (Form 3–1383–C):				
Individuals	160	160	1	160
Private Sector	100	100	1	100
Government	27	27	1	27
Research and Monitoring Special Use Application (Form 3–1383–R):				
Individuals	104	104	5	520
Private Sector	201	201	5	1,005
Government	67	67	5	335
<i>ePermits</i> —Research and Monitoring Special Use Application (Form 3–1383–R):				
Individuals	105	105	4.75	499
Private Sector	202	202	4.75	960
Government	68	68	4.75	323
Amendments—Research and Monitoring Special Use Application (Form 3–1383–R):				
Individuals	10	10	1.5	15
Private Sector	20	20	1.5	30
Government	7	7	1.5	11
<i>ePermits Amendments</i> —Research and Monitoring Special Use Application (Form 3–1383–R):				
Individuals	10	10	1.25	13
Private Sector	20	20	1.25	25
Government	7	7	1.25	9
Renewals—Research and Monitoring Special Use Application (Form 3–1383–R):				
Individuals	21	21	2	42

Requirement	Annual number of respondents	Total annual responses	Completion time per response (hours)	Total annual burden hours*
Private Sector	40	40	2	80
Government	14	14	2	28
<i>ePermits Renewals</i> —Research and Monitoring Special Use Application (Form 3–1383–R):				
Individuals	21	21	1	21
Private Sector	40	40	1	40
Government	14	14	1	14
Bid Sheet—National Wildlife Refuge System (Form 3–1384):				
Private Sector	125	125	1	125
<i>ePermits</i> —Bid Sheet—National Wildlife Refuge System (Form 3–1384):				
Private Sector	125	125	.75	94
Amendments—Bid Sheet—National Wildlife Refuge System (Form 3–1384):				
Private Sector	13	13	0.33	4
<i>ePermits Amendments</i> —Bid Sheet—National Wildlife Refuge System (Form 3–1384):				
Private Sector	13	13	0.25	3
Activity Reports/Associated Document Requirements:				
Individuals	1,122	1,122	3	3,366
Private Sector	730	730	3	2,190
Government	198	198	3	594
<i>ePermits</i> —Activity Reports/Associated Document Requirements:				
Individuals	1,122	1,122	2	2,244
Private Sector	730	730	2	1,460
Government	198	198	2	396
Amendments—Activity Reports/Associated Document Requirements:				
Individuals	2	2	0.33	1
Private Sector	23	23	0.33	8
Government	5	5	0.33	2
<i>ePermits Amendments</i> —Activity Reports/Associated Document Requirements:				
Individuals	2	2	0.25	1
Private Sector	23	23	0.25	6
Government	5	5	0.25	1
Totals	13,903	13,903		27,919

* 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. 2021–14832 Filed 7–12–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAKC001030/
A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of South Dakota

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the class III gaming compact between the Sisseton-Wahpeton Oyate of the Lake Traverse Reservation (Tribe) and the State of South Dakota (State).

DATES: The compact takes effect on July 13, 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 section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.*, the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Compact allows for an unlimited number of roulette tables,

crap tables, and keno devices. The Compact is approved.

Bryan Newland,
Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2021–14833 Filed 7–12–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212D0102DR/DS5A300000/
DR.5A311.IA000118]

Office of Indian Economic Development, Tribal Tourism Grant Program (TTGP), Part of the NATIVE Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Secretary of the Interior (Secretary), through the Office of Indian Economic Development (OIED), Division of Economic Development (DED), solicits proposals from Indian

Tribes and Tribal organizations (as defined in the NATIVE Act) to receive grants to support Tribal tourism feasibility studies and/or Tribal tourism business plan development. The Program supports Tribes and Tribal organizations to increase their capacity to plan, develop and manage tourism and related infrastructure in support of economic development and the NATIVE Act. The Program will provide funding for Tribes and Tribal organizations to conduct tourism feasibility studies that will empower them to make informed decisions on potential tourism project(s). The Program will also provide funding for Tribes and Tribal organizations to develop business plans on completed tourism feasibility studies. In addition to the feasibility study, tourism grants may fund business plans for Tribal tourism businesses recovering from the economic impacts of the COVID-19 pandemic.

DATES: Grant application packages must be submitted to the *Grants.gov* no later than 9 p.m. Eastern Daylight Time, August 13, 2021. OIED will not consider proposals received after this time and date.

ADDRESSES: The required method of submitting proposals is through *Grants.gov*. For information on how to apply for grants in *Grants.gov*, see the instructions available at <https://www.grants.gov/help/html/help/Applicants/HowToApplyForGrants.htm>. Proposals must be submitted to *Grants.gov* by the deadline established in the **DATES** section.

FOR FURTHER INFORMATION CONTACT: Mr. James R. West, Tribal Tourism Grant Program (TTGP) Manager, Office of Indian Economic Development, Room 6049-B, 12220 Sunrise Valley Drive, Reston, Virginia 20191; telephone: (202) 595-4766; email: jamesr.west@bia.gov. Additional Program information can be found at <https://www.bia.gov/service/grants/ttgp>.

SUPPLEMENTARY INFORMATION:

- I. General Information
- II. Number of Projects Funded
- III. Background
- IV. Eligibility for Funding
- V. Who may perform feasibility studies funded by TTGP grants?
- VI. Applicant Procurement Procedures
- VII. Limitations
- VIII. TTGP Application Guidance
- IX. Mandatory Components
- X. Incomplete Applications
- XI. Review and Selection Process
- XII. Evaluation Criteria
- XIII. Transfer of Funds
- XIV. Reporting Requirements for Award Recipients
- XV. Conflicts of Interest
- XVI. Questions and Requests for OIED

Assistance
XVII. Paperwork Reduction Act
XVIII. Authority

I. General Information

Award Ceiling: \$150,000.
Award Floor: \$25,000.
CFDA Number: 15.133.
Cost Sharing or Matching Requirement: No.
Number of Awards: 20–35.
Category: Business Development.

II. Number of Projects Funded

OIED anticipates award of approximately twenty (20) to thirty-five (35) grants under this announcement ranging in value from approximately \$25,000 to \$150,000. The program can fund projects only one year at a time. OIED will use a competitive evaluation process based on criteria described in the Review and Selection Process section at section XII of this notice.

III. Background

The Office of the Assistant Secretary—Indian Affairs, through OIED, is soliciting proposals from Indian Tribes, as defined in 25 U.S.C. 4352(2), and Tribal organizations, as defined in 25 U.S.C. 4352(4), for grant funding to retain consultants to perform feasibility studies on Tribal tourism and tourism business plan development. The Program supports Tribes and Tribal organizations to increase capacity to plan, develop and manage tourism and related infrastructure in support of economic development and the NATIVE Act (Pub. L. 114–221 (09/23/2016)). Consultants may include universities and colleges, private consulting firms, non-academic/non-profit entities, or others. The feasibility studies will help facilitate informed decision-making regarding Tribes' economic futures. Feasibility studies may concern the viability of a tourism project. In addition to the feasibility study, TTGP grants may fund business plans for proposed businesses or recovering Tribal businesses.

The OIED administers this program through its Division of Economic Development (DED).

These grants will be funded under a non-recurring appropriation of the BIA budget. Congress appropriates funds on a year-to-year basis. Thus, while some projects may extend over several years, funding for successive years depends on each fiscal year's appropriations.

The funding periods and amounts referenced in this solicitation are subject to the availability of funds at the time of award, as well as the Department of the Interior (DOI) and Indian Affairs priorities at the time of the award.

Neither DOI nor Indian Affairs will be held responsible for proposal or application preparation costs. Publication of this solicitation does not obligate DOI or Indian Affairs to award any specific grant or to obligate all or any part of available funds. Future funding is subject to the availability of appropriations and cannot be guaranteed. DOI or Indian Affairs may cancel or withdraw this solicitation at any time.

IV. Eligibility for Funding

Indian Tribes and Tribal organizations, as defined in 25 U.S.C. 4352, are eligible. Note: The U.S. Department of the Interior Office of Native Hawaiian Relations is managing NATIVE Act tourism grants to Native Hawaiian Organizations. For additional information on grants to Native Hawaiian Organizations, please contact Kaiini Kaloi, Director, Office of Native Hawaiian Relations, (202) 208-7462, Kaiini_Kaloi@ios.doi.gov.

V. Who may perform tourism feasibility studies or develop tourism business plans funded by TTGP grants?

The applicant determines who will conduct its feasibility study or business plan. An applicant has several choices, including but not limited to:

- Universities and colleges, including but not limited to Tribal colleges and universities;
- Private consulting firms; or
- Non-academic, non-profit entities.

VI. Applicant Procurement Procedures

The applicant is subject to the procurement standards in 2 CFR 200.318 through 200.326. In accordance with 2 CFR 200.318, an applicant must use its own documented procurement procedures which reflect Tribal laws and regulations, provided that the procurements conform to applicable Federal law and standards identified in title 2 of the Code of Federal Regulations.

VII. Limitations

TTGP grant funding must be expended in accordance with applicable statutory and regulatory requirements, including 2 CFR part 200. As part of the grant application review process, IED may conduct a review of an applicant's prior IED grant awards(s).

Applicants that are currently under BIA sanction Level 2 or higher resulting from non-compliance with the Single Audit Act are ineligible for a TTGP award. Applicants at Sanction Level 1 will be considered for funding.

An applicant may submit more than one grant application; however,

applications should address only one Tribal tourism project per application. Any submissions that contain multiple project proposals will not be considered. OIED will apply the same objective ranking criteria to each proposal.

The purpose of TTGP grants is to fund feasibility studies and business plans for proposed tourism projects. An application can request funding for a feasibility study and a business plan. Applications may also request either a feasibility or a business plan, depending on the Tribe's needs. Generally, feasibility studies cost up to \$50,000 and business plans between \$5,000–\$20,000.

TTGP awards may not be used for:

- Establishing or operating a Tribal office;
- Indirect costs or administrative costs as defined by the Federal Acquisition Regulation (FAR);
- Purchase of equipment that is used to develop the feasibility studies, such as computers, vehicles, field gear, etc. (however, leasing of this type of equipment for the purpose of developing feasibility studies is allowed);
- Creating Tribal jobs to complete the project. An TTGP grant is not intended to create temporary administrative jobs or supplement employment for Tribal members;
- Legal fees;
- Application fees associated with permitting;
- Training;
- Contract negotiation fees;
- Feasibility studies of energy, mineral, energy legal infrastructure, or broadband related projects, businesses, or technologies that are addressed by OIED's Energy and Mineral Development Program (EMDP), Tribal Energy Development Capacity (TEDC); and
- Any other activities not authorized by the grant award letter.

VIII. TTGP Application Guidance

All applications are required to be submitted in digital form to [grants.gov](https://www.grants.gov). For instructions, see <https://www.grants.gov/help/html/help/Applicants/HowToApplyForGrants.htm>. In very limited circumstances, OIED may accept a non-digital application. Please contact OIED at least a week prior to the submission deadline for approval.

IX. Mandatory Components

There are seven mandatory components (forms) that must be included in each proposal package. Links to the mandatory forms can be

found under the “package” tab on the TribalTourismFY2021 grant opportunity page at www.grants.gov. The following are the names of the required forms:

- Application for Federal Assistance (SF–424) [V3.0]
- Budget Information for Non-Construction Programs (SF–424A) [V1.0]
- Budget Narrative Attachment Form [V1.2]
- Project Abstract Summary [V2.0]
- Project Narrative Attachment Form [V1.2]
- Attachments [V1.2]
- Key Contacts [V2.0]

Application for Federal Assistance SF–424

It is required that the applicant complete the Application for Federal Assistance SF–424. Please use a descriptive file name that includes Tribal name and project description. For example: TTGPSF424.Tribalname.Project.

Project Abstract Summary and Project Narrative Attachment

The first paragraph of the project narrative must include the title and basic description of the proposed Tribal tourism feasibility study and/or Tribal tourism business plan. The Project Narrative must not exceed 15 pages. At a minimum, it should include:

- A technical description of the project and, if applicable, an explanation of how the proposed new study and/or business plan would benefit the applicant and does not duplicate previous work;
- A description of the project objectives and goals;
- Deliverable products that the consultant is expected to generate, including interim deliverables (such as status reports and technical data to be obtained) and final deliverables (the feasibility study); and
- Resumes of key consultants and personnel to be retained, if available, and the names of subcontractors, if applicable. This information may be included as an attachment to the application and will not be counted towards the 15-page limitation.
- Please use a descriptive file name that includes Tribal name and project description. For example: TTGPNarrative.Tribalname.Project.

In addition, unless prohibited by Tribal procurement procedures, please include a description of the consultant(s) the applicant wishes to retain, including the consultant's contact information, technical expertise, training, qualifications, and suitability to undertake the feasibility study. These

documents may be included at the end of the Project Narrative and will not be counted toward the 15-page limitation.

Project Narratives are not judged based on their length. Please do not submit any unnecessary attachments or documents beyond what is listed above, e.g., Tribal history, unrelated photos and maps.

Budget Information for Non-Construction Programs (SF–424A) [V1.0] and Budget Narrative Attachment Form [V1.2]

It is required that the budget be submitted using the SF–424A form. Please use a descriptive file name that includes Tribal name and project description. For example: TTGPBudget.Tribalname.Project.

The budget must identify the amount of grant funding requested and a comprehensive breakdown of all projected and anticipated expenditures, including contracted personnel fees, consulting fees (hourly or fixed), travel costs, data collection and analysis costs, computer rentals, report generation, drafting, advertising costs for a proposed project and other relevant project expenses, and their subcomponents.

- Travel costs should be itemized by airfare, vehicle rental, lodging, and per diem, based on the current Federal government per diem schedule.
- Data collection and analysis costs should be itemized in sufficient detail for the IED review committee to evaluate the charges.
- Other expenses may include computer rental, report generation, drafting, and advertising costs for a proposed project.

Key Contacts [V2.0]

Applicants must include the Key Contacts information page that includes:

- Project Manager's contact information including address, email, desk, and cell phone number;
- If there is more than one contact, please provide an additional key contacts form.
- Please use a descriptive file name that includes Tribal name and identifies that it is the critical information page (CIP). For example: TTGPCIP.Tribalname.Project.

Attachments [V1.2]

Utilize the *attachments form* to include the Tribal resolution issued in the fiscal year of the grant application, authorizing the submission of a FY 2021 TTGP grant application. It must be signed by authorized Tribal representative(s). The Tribal resolution must also include a description of the

feasibility study and/or business plan to be developed. The attachments form can also be used to include any other attachments related to the proposal.

Special Note

Please make sure that SAM number used to apply is active, not expired;

Please make sure an *active* Automated Standard Application for Payment (ASAP) number is provided. Applicants *must* have an ASAP number to be eligible;

It is helpful to list counties where the project is located and congressional district number where the project is located.

X. Incomplete Applications

Applications submitted without one or more of the five mandatory components described above will be returned to the applicant with an explanation. The applicant will then be allowed to correct any deficiencies and resubmit the proposal for consideration on or before the deadline. This option will not be available to an applicant once the deadline has passed.

XI. Review and Selection Process

Upon receiving a TTGP application, OIED will determine whether the application is complete and that the proposed project does not duplicate or overlap previous or currently funded OIED tourism projects. Any proposal that is received after the date and time in the **DATES** section of this notice will not be reviewed. If an application is not complete and the submission deadline has not passed, the applicant will be notified and given an opportunity to resubmit its application.

The OIED Review Committee, comprised of OIED staff, staff from other Federal agencies, and subject matter experts, will evaluate the proposals against the ranking criteria. Proposals will be evaluated using the five ranking criteria listed below, with a maximum achievable total of 100 points.

Final award selections will be approved by the Assistant Secretary—Indian Affairs and the Associate Deputy Secretary, U.S. Department of the Interior. Applicants not selected for award will be notified in writing.

XII. Evaluation Criteria

Proposals (both feasibility and business plans) will be formally evaluated by an OIED review committee using the five criteria listed below. Each criterion provides a percentage of the total maximum rating of 100 points.

The Project's Economic Benefits: 50 points.

Project Deliverables: 20 Points.

Feasibility Process and Analysis: 10 points.

Costs of Proposal: 10 points.

Specificity: 10 points.

The Project's Economic Benefits: 50 Points

The reviewers will determine if the proposal's scope of work clearly states the tourism opportunity to be studied. Factors that the reviewers will consider when awarding points are, but not limited to:

- Does the tourism proposal address what is needed to increase tourism capacity?

- Does the proposal describe the benefits that the tourism project would have if implemented?

- Does the proposal describe i how the project will address economic development challenges—such as unemployment, workforce development, and infrastructure needs—and stimulate economic activity within a Native community?

- Does the proposal address sustainability planning, ensuring that the project has long-term benefits for the community?

- Does the proposal identify any partnerships with non-profit or private sector resources that might increase the potential that the tourism project will succeed?

Project Deliverables: 20 Points

The reviewers will determine if the proposal describes in detail applicable proposed deliverables. For example, a mountain biking tour study would include deliverables such as, but not limited to, site analysis, market demographics, marketing strategies, drive-time market, regional competition, market demands, and a financial model that includes investment and return on investment projections.

Project Tasks and Timeline: 10 Points

The reviewers will determine if a comprehensive timeline has been developed to address tasks that are needed to successfully complete the objectives outlined in the scope of work.

Costs of Proposal/Budget: 10 Points

The reviewers will assess the costs listed in the budget to determine if the overall value of the project is competitively priced and in accordance with the goals stated within the proposal/scope of work.

Specificity: 10 Points

In addition, the reviewers understand that applicants may retain consultant(s) that prepare the Tourism proposal to also conduct the feasibility study if the

grant is awarded. This does not prejudice an applicant's chances of being selected as a grantee. However, the Committee will view unfavorably proposals that show little evidence of communication between the consultant(s) and the applicant or scant regard for the applicant community's unique circumstances. Facsimile applications prepared by the same consultant(s) and submitted by multiple applicants will receive scrutiny in this regard.

XIII. Transfer of Funds

IED's obligation under this solicitation is contingent on receipt of congressionally appropriated funds. No liability on the part of the U.S. Government for any payment may arise until funds are made available to the awarding officer for this grant and until the recipient receives notice of such availability, to be confirmed in writing by the grant officer.

All payments under this agreement will be made by electronic funds transfer through the ASAP. All award recipients are required to have a current and accurate DUNS number to receive funds. All payments will be deposited to the banking information designated by the applicant in the System for Award Management (SAM).

XIV. Reporting Requirements for Award Recipients

The applicant must deliver all products and data required by the signed Grant Agreement for the proposed TTGP feasibility study and business plan project to OIED within 30 days of the end of each reporting period and 90 days after completion of the project. The reporting periods will be established in the terms and conditions of the final award.

OIED requires that deliverable products be provided in digital format. Reports can be provided in either Microsoft Word or Adobe Acrobat PDF format. Spreadsheet data can be provided in Microsoft Excel, Microsoft Access, or Adobe PDF formats. All vector figures should be converted to PDF format. Raster images can be provided in PDF, JPEG, TIFF, or any of the Windows metafile formats. The contract between the grantee and the consultant conducting the TTGP funded feasibility study must include deliverable products and require that the products be prepared in the format described above.

The contract should include budget amounts for all printed and digital copies to be delivered in accordance with the grant agreement. In addition, the contract must specify that all

products generated by a consultant belong to the grantee and cannot be released to the public without the grantee's written approval. Products include, but are not limited to, all reports and technical data obtained, maps, status reports, and the final report.

In addition, this funding opportunity and financial assistance award must adhere to the following provisions.

XV. Conflicts of Interest

Applicability

- This section intends to ensure that non-Federal entities and their employees take appropriate steps to avoid conflicts of interest in their responsibilities under or with respect to Federal financial assistance agreements.

- In the procurement of supplies, equipment, construction, and services by recipients and by sub-recipients, the conflict of interest provisions in 2 CFR 200.318 apply.

Requirements

- Non-Federal entities must avoid prohibited conflicts of interest, including any significant financial interests that could cause a reasonable person to question the recipient's ability to provide impartial, technically sound, and objective performance under or with respect to a Federal financial assistance agreement.

- In addition to any other prohibitions that may apply with respect to conflicts of interest, no key official of an actual or proposed recipient or sub-recipient, who is substantially involved in the proposal or project, may have been a former Federal employee who, within the last one (1) year, participated personally and substantially in the evaluation, award, or administration of an award with respect to that recipient or sub-recipient or in development of the requirement leading to the funding announcement.

- No actual or prospective recipient or sub-recipient may solicit, obtain, or use non-public information regarding the evaluation, award, administration of an award to that recipient or sub-recipient or the development of a Federal financial assistance opportunity that may be of competitive interest to that recipient or sub-recipient.

Notification

- Non-Federal entities, including applicants for financial assistance awards, must disclose in writing any conflict of interest to the DOI awarding agency or pass-through entity in accordance with 2 CFR 200.112, Conflicts of Interest.

- Recipients must establish internal controls that include, at a minimum, procedures to identify, disclose, and mitigate or eliminate identified conflicts of interest. The recipient is responsible for notifying the Financial Assistance Officer in writing of any conflicts of interest that may arise during the life of the award, including those that have been reported by sub-recipients.

- *Restrictions on Lobbying.* Non-Federal entities are strictly prohibited from using funds under this grant or cooperative agreement for lobbying activities and must provide the required certifications and disclosures pursuant to 43 CFR part 18 and 31 U.S.C. 1352.

- *Review Procedures.* The Financial Assistance Officer will examine each conflict of interest disclosure on the basis of its particular facts and the nature of the proposed grant or cooperative agreement, and will determine whether a significant potential conflict exists and, if it does, develop an appropriate means for resolving it.

- *Enforcement.* Failure to resolve conflicts of interest in a manner that satisfies the Government may be cause for termination of the award. Failure to make the required disclosures may result in any of the remedies described in 2 CFR 200.338, Remedies for Noncompliance, including suspension or debarment (see also 2 CFR part 180).

Data Availability

- *Applicability.* The Department of the Interior is committed to basing its decisions on the best available science and providing the American people with enough information to thoughtfully and substantively evaluate the data, methodology, and analysis used by the Department to inform its decisions.

- *Use of Data.* The regulations at 2 CFR 200.315 apply to data produced under a Federal award, including the provision that the Federal Government has the right to obtain, reproduce, publish, or otherwise use the data produced under a Federal award as well as authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

- *Availability of Data.* The recipient shall make the data produced under this award and any subaward(s) available to the Government for public release, consistent with applicable law, to allow meaningful third-party evaluation and reproduction of the following:

- The scientific data relied upon;
- The analysis relied upon; and
- The methodology, including models, used to gather and analyze data.

XVI. Questions and Requests for IED Assistance

OIED staff may provide technical consultation, upon written request by an applicant. The request must clearly identify the type of assistance sought. Technical consultation does not include funding to prepare a grant proposal, grant writing assistance, or pre-determinations as to the likelihood that a proposal will be awarded. The applicant is solely responsible for preparing its grant proposal. Technical consultation may include clarifying application requirements, confirming whether an applicant previously submitted the same or similar proposal, and registration information for SAM or ASAP.

XVII. Paperwork Reduction Act

The information collection requirements contained in this notice have been reviewed and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3504(h). The OMB control number is 4040-0004. The authorization expires on 12/31/2022. An agency may not conduct or sponsor, and you are not required to respond to, any information collection that does not display a currently valid OMB Control Number.

XVIII. Authority

This is a discretionary grant program authorized under the NATIVE Act (25 U.S.C. 4354(b)). The NATIVE Act authorizes the head of an agency with assets or resources relating to travel, recreation, or tourism promotion or branding enhancement for which Indian Tribes, Tribal organizations, or Native Hawaiian organizations are eligible may be used: (1) To support the efforts of Indian Tribes, Tribal organizations, and Native Hawaiian organizations to tell the story of Native Americans as the First Peoples of the United States; (2) to use the arts and humanities to help revitalize Native communities, promote economic development, increase livability, and present the uniqueness of the United States to visitors in a way that celebrates the diversity of the United States; and to carry out 25 U.S.C. 4354.

Bryan Newland,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2021-14835 Filed 7-12-21; 8:45 am]

BILLING CODE 4337-10-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAKC001030/
A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Fourth Amendment to the Tribal-State Compact for Class III Gaming between the Snoqualmie Indian Tribe (Tribe) and the State of Washington (State).

DATES: The compact takes effect on July 13, 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 section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100-497, 25 U.S.C. 2701 *et seq.*, the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Compact expands the types of payments allowed, updates references to State law citations, specifies Federal court jurisdiction for dispute resolution, adds recipients who may receive contributions from the smoking cessation and prevention funds, adds Appendix D, which regulates limitations on wagers, credit, facilities, and problem gaming resources and contributions. The Compact also adds Appendix W, which contains rules governing wide area progressives. The Compact is approved.

Bryan Newland,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2021-14834 Filed 7-12-21; 8:45 am]

BILLING CODE 4337-15-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-468 and 731-TA-1166-1167 (Second Review)]

Scheduling of Expedited Five-Year Reviews; Certain Magnesita Carbon Bricks From China and Mexico

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the countervailing duty order on certain magnesita carbon bricks from China and the antidumping duty orders on certain magnesita carbon bricks from China and Mexico would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: April 9, 2021.

FOR FURTHER INFORMATION CONTACT: Tyler Berard (202-205-3354), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these reviews may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On April 9, 2021, the Commission determined that the domestic interested party group response to its notice of institution (86 FR 126, January 4, 2021) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.¹ Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the

Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary’s Office will accept only electronic filings at this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on July 9, 2021, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission’s rules.

Written submissions.—As provided in section 207.62(d) of the Commission’s rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,² and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before July 16, 2021, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by July 16, 2021. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s *Handbook on Filing Procedures*, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates

² The Commission has found a response to its notice of institution filed by the Magnesita Carbon Bricks Fair Trade Committee, an ad hoc association on behalf of its members, Resco Products, Inc., Magnesita Refractories Company, and Harbison Walker International, Inc., domestic producers of certain magnesita carbon bricks, to each be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

¹ A record of the Commissioners’ votes is available from the Office of the Secretary and at the Commission’s website.

upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.
Issued: July 7, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–14770 Filed 7–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1047 (Third Review)]

Ironing Tables and Certain Parts Thereof From China; Scheduling of Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the antidumping duty order on ironing tables and certain parts thereof from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: May 7, 2021.

FOR FURTHER INFORMATION CONTACT: Tyler Berard (202–205–3354), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On May 7, 2021, the Commission determined that the domestic interested party group response to its notice of institution (86 FR 7737, February 1, 2021) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.¹ Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on July 9, 2021, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,² and any party other than an interested party to the review may file written comments with the Secretary on what determination the

¹ A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

² The Commission has found the response to its notice of institution filed on behalf of Home Products International, Inc., (“HPI”), the sole domestic producer of ironing tables and certain parts thereof, to be individually adequate. Comments from other interested parties will not be accepted (see 19 CFR 207.62(d)(2)).

Commission should reach in the review. Comments are due on or before July 16, 2021, and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by July 16, 2021. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 7, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–14808 Filed 7–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–469 and 731–TA–1168 (Second Review)]

Certain Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From China; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the countervailing and antidumping duty orders on certain seamless carbon and alloy steel standard, line, and pressure pipe from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: May 7, 2021.

FOR FURTHER INFORMATION CONTACT:

Alejandro Orozco (202–205–3177), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these reviews may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On May 7, 2021, the Commission determined that the domestic interested party group response to its notice of institution (86 FR 7740, February 1, 2021) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.¹ Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary’s Office will accept only electronic filings at this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-

based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on July 16, 2021, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission’s rules.

Written submissions.—As provided in section 207.62(d) of the Commission’s rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,² and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before July 23, 2021 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by July 23, 2021. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s *Handbook on Filing Procedures*, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

² The Commission has found a joint response to its notice of institution on behalf of (1) United States Steel Corporation; (2) Vallourec Star, L.P.; (3) BENTELER Steel/Tube Manufacturing Corp.; and (4) Tenaris Bay City, Inc./IPSCO Tubulars Inc., domestic producers of certain seamless carbon and alloy steel standard, line, and pressure pipe, to each be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission’s rules.

By order of the Commission.

Issued: July 7, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–14810 Filed 7–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–654–655 and 731–TA–1530–1532 (Final)]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From Korea, Russia, and Ukraine; Scheduling of the Final Phase of the Anti-Dumping and Countervailing Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: July 2, 2021.

FOR FURTHER INFORMATION CONTACT:

Lawrence Jones ((202) 205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these investigations may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective December 15, 2020, the Commission established a general schedule for the conduct of the final phase of its investigations on seamless carbon and alloy steel standard, line, and pressure pipe from Czechia, Korea, Russia, and Ukraine¹ following preliminary determinations by the U.S. Department

¹ A record of the Commissioners’ votes is available from the Office of the Secretary and at the Commission’s website.

¹ 85 FR 86946, December 31, 2020.

of Commerce (“Commerce”) that imports of seamless carbon and alloy steel standard, line, and pressure pipe from Korea and Russia were being subsidized by the governments of Korea and Russia and imports of seamless carbon and alloy steel standard, line, and pressure pipe from Czechia were being sold in the United States at less than fair value (“LTFV”).² Notice of the scheduling of the final phase of the Commission’s investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on December 31, 2020, (85 FR 86946). In light of the restrictions on access to the Commission building due to the COVID-19 pandemic, the Commission conducted its hearing through written testimony and video conference on March 4, 2021. All persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission subsequently issued its final determination that an industry in the United States was materially injured by reason of imports of seamless carbon and alloy steel standard, line, and pressure pipe from Czechia that Commerce had determined were sold at LTFV in the United States.³ On July 2, 2021, Commerce issued its final affirmative determinations that imports of seamless carbon and alloy steel standard, line, and pressure pipe from Korea, Russia, and Ukraine were being sold at LTFV in the United States and subsidized by the governments of Korea and Russia.⁴ Accordingly, the Commission currently is issuing a supplemental schedule for its antidumping and countervailing duty investigations on imports of seamless carbon and alloy steel standard, line, and pressure pipe from Korea, Russia, and Ukraine.

This supplemental schedule is as follows: The deadline for filing supplemental party comments on Commerce’s final antidumping and countervailing duty determinations is July 9, 2021. Supplemental party comments may address only Commerce’s final antidumping and countervailing duty determinations regarding imports of seamless carbon and alloy steel standard, line, and pressure pipe from Korea, Russia, and Ukraine. These supplemental final

comments may not contain new factual information and may not exceed five (5) pages in length. The supplemental staff report in the final phase of these investigations regarding subject imports from Korea, Russia, and Ukraine will be placed in the nonpublic record on July 23, 2021; and a public version will be issued thereafter.

For further information concerning these investigations see the Commission’s notice cited above and the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Please note the Secretary’s Office will accept only electronic filings during this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission’s rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission’s rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission’s rules.

By order of the Commission.

Issued: July 7, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021-14809 Filed 7-12-21; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121-0065]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection: National Corrections Reporting Program

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 13, 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 Danielle Kaeble, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Danielle.Kaeble@usdoj.gov; telephone: 202-598-1024).

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 Bureau of Justice Statistics, 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

² 85 FR 80024 and 85 FR 80007, December 11, 2020; 85 FR 83059, December 21, 2020.

³ 86 FR 21763, April 23, 2021.

⁴ 86 FR 35263-35274, July 2, 2021.

of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *The Title of the Form/Collection:* National Corrections Reporting Program. The collection includes the following parts: Prisoner Admission Report, Prisoner Release Report, Prisoners in Custody at Year-end Report, Post-Custody Community Supervision Entry Report, Post-Custody Community Supervision Exit Report.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number(s): NCRP-1A, NCRP-1B, NCRP-1D, NCRP-1E, NCRP-1F. The applicable component within the Department of Justice is the Bureau of Justice Statistics (Corrections Unit), in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: 50 state departments of corrections (DOCs) and 7 parole boards (in six states and the District of Columbia). The National Corrections Reporting Program (NCRP) is the only national data collection furnishing annual individual-level information for state prisoners at five points in the incarceration process: Prison admission, prison release, annual year-end prison custody census, entry to post-custody community corrections supervision, and exits from post-custody community corrections supervision. The Bureau of Justice Statistics (BJS), the U.S. Congress, researchers, and criminal justice practitioners use these data to describe annual movements of adult offenders through state correctional systems, as well as to examine long-term trends in time served in prison, demographic and offense characteristics of inmates, sentencing practices in the states that submit data, transitions between incarceration and community corrections, and recidivism. Providers of the data are personnel in the states' Departments of Corrections and Parole, and all data are submitted on a voluntary basis. The NCRP collects the following administrative data on each inmate in participating states' custody:

- County of sentencing
- State and federal inmate identification numbers
- Dates of: Birth, prison admission, prison release, projected prison release, mandatory prison release, eligibility hearing for post-custody community corrections supervision,

post-custody community corrections supervision entry, post-custody community corrections supervision exit

- First, middle, and last names
- Demographic information: Sex, race, Hispanic origin, education level, prior military service, date and type of last discharge from military
- Offense type and number of counts per inmate for a maximum of three convicted offenses per inmate
- Total sentence length imposed
- Type of facility where inmate is serving sentence (for year-end custody census records only, the name of the facility is also requested)
- Country of current citizenship, country of birth, and status of current U.S. citizenship
- Type of prison admission
- Type of prison release
- Location of post-custody community supervision exit or post-custody community supervision office (post-custody community supervision records only)
- Social security number
- Address of last residence prior to incarceration
- Prison security level at which the inmate is held

BJS is not proposing making additions or deletions from the previously approved collection.

BJS uses the information gathered in NCRP in published reports and statistics. The reports will be made available to the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, others interested in criminal justice statistics, and the general public via the BJS website.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* BJS anticipates 57 respondents to NCRP by 2024: 50 state DOC respondents and seven separate parole boards (in six states and the District of Columbia). Burden hours for the three collection years (2022–2024) differ based on whether a state has previously submitted NCRP prison and PCCS data in recent years. All 50 DOCs have recently submitted NCRP prison data, but currently, only 35 DOCs have submitted PCCS data in the last four years.

Burden Hours for Prison Records (NCRP-1A, NCRP-1B, NCRP-1D)

All 50 DOCs have recently submitted NCRP prison data, so the average time needed to continue providing prison data is expected to be 7 hours per respondent for both prisoner admissions and releases (NCRP-1A and NCRP-1B)

and 7 hours for data on persons in prison at year-end (NCRP-1D). For 2022–2024, the total burden estimate of 14 hours per DOC for a total of 700 hours annually for the 50 DOCs (14 hours*50 = 700 hours). This is the same estimate as given for the 2021 collection since BJS is not requesting changes to the collection.

Burden Hours for PCCS Records (NCRP-1E, NCRP-1F)

There are currently 37 jurisdictions submitting PCCS data (32 DOCs and 5 parole boards), and BJS estimates that extraction and submission of both the PCCS entries and exits takes an average of 8 hours per jurisdiction. In 2022, BJS anticipates that 3 additional DOCs and one parole board will submit data, with the burden for each new jurisdiction being 24 hours to set up extraction programs and make the submission. Thus, the burden for PCCS records is 296 hours for those already submitting (8 hours*37 = 296 hours), and 96 hours for new submissions (24 hours*4 = 96). The total amount of time for all PCCS submissions in 2022 is 392 hours.

In 2023, BJS hope to recruit an additional 7 DOCs and the remaining parole board to submit NCRP PCCS data. The total estimate for submission of PCCS for new jurisdictions in 2023 is 192 hours (24 hours*8 = 192 hours). For those 40 DOCs and 6 parole boards currently responding, provision of the PCCS data in 2023 will total 368 hours (8 hours*46 = 368 hours). The total amount of time for all PCCS submissions in 2023 is 560 hours.

Similarly, BJS hopes that the remaining 2 DOCs will submit PCCS data for the first time in 2024. The remaining non-reporting DOCs would need a total of 48 hours to create data extraction programs and begin data submission (24 hours*2 = 48 hours). Those jurisdictions (42 DOCs and 7 parole boards) who provided NCRP PCCS data in 2023 will require 392 hours total to do the same in 2024 (8 hours*49 = 392 hours). The total amount of time for all PCCS submissions in 2024 is 440 hours.

Burden Hours for Data Review/Follow-Up Consultations

Follow-up consultations with respondents are usually necessary while processing the data to obtain further information regarding the definition, completeness and accuracy of their report. The duration of these follow-up consultations will vary based on the number of record types submitted, so BJS has estimated an average of 3 hours per jurisdiction to cover all of the records (prison and/or PCCS) submitted.

In 2022, BJS anticipates that one of the two parole boards not currently submitting PCCS data will begin to submit, so the number of jurisdictions requiring follow-up consultations is 51 (50 DOCs submitting at least the prison data, and one parole board submitting only PCCS data). This yields a total of 153 hours of follow-up consultation after submission (3 hours*51 = 153 hours).

This total estimate of 153 hours for data review/follow-up consultations remains the same for 2023 and 2024.

Total Burden Hours for Submitting NCRP Data

BJS anticipates that the total burden for provision and data follow-up of all NCRP data across the participating jurisdictions in 2022–2024 to be 1,293 hours (700 hours for prison records, 440 hours for PCCS records, and 153 hours for follow-up consultation).

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,293 total burden hours associated with this collection in 2022–2024.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: July 8, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–14831 Filed 7–12–21; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Fair Labor Standards Act Special Employment Provisions

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour Division (WHD)-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 August 12, 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:

Crystal Rennie by telephone at 202–693–0456 or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This information collection pertains to the Fair Labor Standards Act (FLSA), 29 U.S.C. 201, *et seq.*, special employment provisions. These provisions relate to restrictions on industrial homework and to the use of special certificates that allow for the employment of categories of workers who may be paid less than the general Federal statutory minimum wage to the extent necessary to prevent curtailment of their employment opportunities. For this revision request specifically, the Department proposes to revise forms WH–226 (Application for Authority to Employ Workers with Disabilities at Special Minimum Wages) and WH–226A (Supplemental Data Sheet for Application for Authority to Employ Workers with Disabilities at Special Minimum Wages). The proposed change is to provide an electronic form for the public’s use when completing the WH–226 and/or WH–226A forms. An online platform has been created so the WH–226 and WH–226A forms may be submitted electronically. The substance of the proposed electronic forms is substantially the same with minor word changes to accommodate the type of submission (electronic versus paper). For additional substantive information about this ICR, see the related notice

published in the **Federal Register** on March 17, 2021 (86 FR 14648).

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–WHD.

Title of Collection: Fair Labor Standards Act Special Employment Provisions.

OMB Control Number: 1235–0001.

Affected Public: Private Sector, Businesses or other for-profits, Not-for-profit.

Total Estimated Number of Respondents: 335,271.

Total Estimated Number of Responses: 1,329,967.

Total Estimated Annual Time Burden: 684,595 hours.

Total Estimated Annual Other Costs Burden: \$1,085.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–14813 Filed 7–12–21; 8:45 am]

BILLING CODE 4510–27–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 August 12, 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 Mackie Malaka at (703) 548–2704, emailing PRAComments@ncua.gov, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0193.

Type of Review: Extension of a currently approved collection.

Title: Joint Standards for Assessing the Diversity Policies and Practices.

Abstract: Section 342 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Act) required the NCUA, the Office of the Comptroller of the Currency (OCC), Board of Governors of the Federal Reserve System (Board), Federal Deposit Insurance Corporation (FDIC), Bureau of Consumer Financial Protection (CFPB), and Securities and Exchange Commission (SEC) (Agencies) each to establish an Office of Minority and Women Inclusion (OMWI) to be responsible for all matters of the Agency relating to diversity in management, employment, and business activities. The Act also instructed each OMWI Director to develop standards for assessing the diversity policies and practices of entities regulated by the Agency. The Agencies worked together to develop joint standards, and on June 10, 2015, they jointly published in the **Federal Register** the “Final Interagency Policy Statement Establishing Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies.”

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 2,600.

By Melane Conyers-Ausbrooks, Secretary of the Board, the National Credit Union Administration, on July 7, 2021.

Dated: July 7, 2021.

Mackie I. Malaka,

NCUA PRA Clearance Officer.

[FR Doc. 2021–14780 Filed 7–12–21; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Subject 30-Day Notice of a Tribal Consultation Meeting

AGENCY: National Endowment for the Arts, National Foundation on the Arts and the Humanities.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA) is an independent federal agency whose funding helps to support cultural programs nationwide. Established in 1965, the NEA’s operating budget in FY20 was \$162 million, which is utilized in the form of project and partnership grants, special initiatives, and honorific fellowships to support arts learning, affirm and celebrate America’s rich and diverse cultural heritage, and to extend and promote equal access to the arts in every community. On April 7, 2021, the NEA convened a Tribal Consultation with the goal of developing a formal Tribal Consultation Policy. The draft policy will be the basis of our August 10 consultation call. More information about the NEA’s work with Native Arts and Culture is available here: <https://www.arts.gov/impact/native-arts-and-culture>.

DATES: Tuesday, August 10, 2021, 2:00–3:30 p.m. (EDT); Written comments must be sent by August 24, 2021.

ADDRESSES: The August 10 meeting will be held virtually, via Zoom. Tribal leaders may register to participate through https://www.zoomgov.com/webinar/register/WN_hWsn1qERCWZOLN8m-uC_g to receive the Zoom link. Tribal communities also can submit written comments by August 24 to NativeArts@arts.gov with the subject line: “Comments for August 10, 2021 NEA Tribal Consultation Meeting.”

SUPPLEMENTARY INFORMATION: In alignment with the January 26, 2021 Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships and Executive Order 13175, NEA invites Tribal leaders to discuss their needs and concerns related to NEA resources and NEA’s draft Tribal Consultation policy in this meeting. The draft NEA Tribal Consultation Policy and a framing document with supplemental readings can be downloaded on the agency’s website:

1. *Draft NEA Tribal Consultation Policy:* <https://www.arts.gov/sites/default/files/Tribal-Consultation-Policy-DRAFT-7.9.21.pdf>.

2. *Framing Document:* <https://www.arts.gov/sites/default/files/NEA-August-2021-Framing-Document.pdf>.

NEA plans to consider this input for incorporation into our Tribal Consultation policy and support we provide to Tribal communities across the U.S. The meeting agenda will be:

1. Input on NEA’s draft Tribal Consultation policy.
2. Barriers for tribal communities to access NEA resources.

FOR FURTHER INFORMATION CONTACT:

Clifford Murphy, Director of Folk & Traditional Arts, phone: 202–682–5726, or by email to murphyc@arts.gov or NativeArts@arts.gov.

Reasonable Accommodation: Anyone who needs an interpreter or other accommodation should email Clifford Murphy, Director of Folk & Traditional Arts, phone: 202–682–5726, or by email to murphyc@arts.gov or NativeArts@arts.gov by 5:00 p.m. (EDT) on August 3, 2021.

Dated: July 7, 2021.

Meghan Jugder,

Support Services Specialist, Office of Administrative Services & Contracts, National Endowment for the Arts.

[FR Doc. 2021–14811 Filed 7–12–21; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0136]

Monthly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Monthly notice.

SUMMARY: Pursuant to section 189.a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular monthly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person. This monthly notice includes all amendments issued, or proposed to be

issued, from May 27, 2021, to June 24, 2021. The last monthly notice was published on June 15, 2021.

DATES: Comments must be filed by August 12, 2021. A request for a hearing or petitions for leave to intervene must be filed by September 13, 2021.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2021–0136. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Paula Blechman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2242, email: Paula.Blechman@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0136, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2021–0136.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–

415–4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at pdr.resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2021–0136, facility name, unit number(s), docket number(s), application date, and subject, in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown below, the Commission finds that the licensees’ analyses provided, consistent with title 10 of the *Code of Federal Regulations* (10 CFR) section 50.91, are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission’s regulations in 10 CFR 50.92, operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously

evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission’s “Agency Rules of Practice and Procedure” in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC’s regulations are accessible electronically from the NRC Library on the NRC’s website at <https://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and

telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC.

The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as discussed below, is granted. Detailed guidance on electronic submissions is located in the Guidance for Electronic Submissions to the NRC (ADAMS Accession No. ML13031A056) and on the NRC website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system timestamps the document and sends the submitter an email

confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting

documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly

available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The table below provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensees' proposed NSHC determinations. For further details with respect to these license amendment applications, see the applications for amendment, which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

LICENSE AMENDMENT REQUEST(S)

Dominion Energy South Carolina, Inc.; Virgil C. Summer Nuclear Station, Unit 1, Fairfield County, SC

Docket No(s)	50-395.
Application date	May 27, 2021.
ADAMS Accession No	ML21147A377.
Location in Application of NSHC	Pages 1-2 of Attachment 4.
Brief Description of Amendment(s)	The proposed amendment would revise the Virgil C. Summer Nuclear Station, Unit 1, Technical Specification 6.3, "Unit Staff Qualifications," by relocating the unit staff qualifications to the Dominion Energy Nuclear Facility Quality Assurance Program Description consistent with guidance contained in the NRC Administrative Letter (AL) 95-06, "Relocation of Technical Specification Administrative Controls to Quality Assurance."
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	W. S. Blair, Senior Counsel, Dominion Resource Services, Inc., 120 Tredegar St., RS-2, Richmond, VA 23219.
NRC Project Manager, Telephone Number	Stephanie Devlin-Gill, 301-415-5301.

Energy Northwest; Columbia Generating Station; Benton County, WA

Docket No(s)	50-397.
Application date	April 28, 2021.
ADAMS Accession No	ML21118A812.
Location in Application of NSHC	Pages 9-10 of Enclosure 1.
Brief Description of Amendment(s)	The proposed amendment would remove License Condition (LC) 2.C.(34) and revise LC 2.C.(35) for Columbia Generating Station (Columbia). LC 2.C.(34) is no longer applicable as the Columbia Final Safety Analysis Report has been updated to include the License Renewal (LR) commitments set forth in NUREG-2123, "Safety Evaluation Report Related to the License Renewal of Columbia Generating Station," published May 2012. The revision to LC 2.C.(35) would clarify that future changes to the LR commitments, as dictated by operating experience, would be made under the provisions of 10 CFR 50.59, "Changes, tests, and experiments."
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Kathleen Galioto, Assistant General Counsel, Energy Northwest, MD PE13, P.O. Box 968, Richland, WA 99352.
NRC Project Manager, Telephone Number	Mahesh Chawla, 301-415-8371.

Energy Northwest; Columbia Generating Station; Benton County, WA

Docket No(s)	50-397.

LICENSE AMENDMENT REQUEST(S)—Continued

Application date	May 8, 2021.
ADAMS Accession No	ML21130A573.
Location in Application of NSHC	Pages 3–4 of Enclosure 1.
Brief Description of Amendment(s)	The proposed amendment would alter Surveillance Requirement (SR) 3.3.1.1.2 of Technical Specification (TS) 3.3.1.1, “Reactor Protection System (RPS) Instrumentation.” This proposed change would revise the SR to verify that calculated (i.e., calorimetric heat balance) power is no more than 2 percent greater than the average power range monitor (APRM) channel output. The SR requires the APRM channel to be adjusted such that calibrated power is no more than 2 percent greater than the APRM indicated power when operating at greater than or equal to 25 percent of rated thermal power. The proposed change is consistent with Technical Specifications Task Force (TSTF) Traveler TSTF–546, Revision 0, “Revise APRM Channel Adjustment Surveillance Requirement.”
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Kathleen Galioto, Assistant General Counsel, Energy Northwest, MD PE13, P.O. Box 968, Richland, WA 99352.
NRC Project Manager, Telephone Number	Mahesh Chawla, 301–415–8371.

Entergy Operations, Inc.; Waterford Steam Electric Station, Unit 3; St. Charles Parish, LA

Docket No(s)	50–382.
Application date	May 28, 2021.
ADAMS Accession No	ML21148A104.
Location in Application of NSHC	Pages 4–5 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendment would revise the technical specifications (TSs) in accordance with Technical Specifications Task Force (TSTF) Traveler TSTF–563, Revision 0, “Revise Instrument Testing Definitions to Incorporate the Surveillance Frequency Control Program,” dated May 10, 2017 (ADAMS Accession No. ML17130A819). TSTF–563 revises the TS definitions of Channel Calibration and Channel Functional Test, which currently permit performance by any series of sequential, overlapping, or total channel steps, to allow the required frequency for testing the components or devices in each step to be determined in accordance with the TS Surveillance Frequency Control Program. The NRC issued a final safety evaluation approving TSTF–563, Revision 0, on December 4, 2018 (ADAMS Accession No. ML18333A152).
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Anna Vinson Jones, Senior Counsel, Entergy Services, Inc., 101 Constitution Avenue NW, Suite 200 East, Washington, DC 20001.
NRC Project Manager, Telephone Number	Perry Buckberg, 301–415–1383.

Exelon FitzPatrick, LLC and Exelon Generation Company, LLC; James A FitzPatrick Nuclear Power Plant; Oswego County, NY,

Docket No(s)	50–333.
Application date	April 16, 2021.
ADAMS Accession No	ML21109A113.
Location in Application of NSHC	Pages 5–7 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendment would revise certain technical specification (TS) requirements related to the reactor pressure vessel (RPV) water inventory control (WIC) for James A. FitzPatrick Nuclear Power Plant. The proposed changes are based on Technical Specifications Task Force (TSTF) Traveler TSTF–582, Revision 0, “RPV WIC Enhancements” (ADAMS Accession No. ML19240A260). The proposed changes also include other administrative changes to the TSs.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Donald P. Ferraro, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Suite 305, Kennett Square, PA 19348.
NRC Project Manager, Telephone Number	Justin Poole, 301–415–2048.

Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE

Docket No(s)	50–298.
Application date	May 11, 2021.
ADAMS Accession No	ML21132A062.
Location in Application of NSHC	Pages 7–9 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would adopt Technical Specifications Task Force (TSTF) Traveler TSTF–582, “RPV WIC [Reactor Pressure Vessel Water Inventory Control] Enhancements,” at the Cooper Nuclear Station. The Technical Specifications related to RPV WIC would be revised to incorporate operating experience and to correct errors and omissions in TSTF–542, Revision 2, “Reactor Pressure Vessel Water Inventory Control.”
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	John C. McClure, Nebraska Public Power District, P.O. Box 499, Columbus, NE 68602–0499.
NRC Project Manager, Telephone Number	Thomas Wengert, 301–415–4037.

Nine Mile Point Nuclear Station, LLC and Exelon Generation Company, LLC; Nine Mile Point Nuclear Station, Unit 2; Oswego County, NY

Docket No(s)	50–410.
Application date	May 26, 2021.

LICENSE AMENDMENT REQUEST(S)—Continued

ADAMS Accession No	ML21146A045.
Location in Application of NSHC	Attachment 1, pages 4–6.
Brief Description of Amendment(s)	The proposed amendment would revise Technical Specification (TS) 3.8.3, “Diesel Fuel Oil, Lube Oil, and Starting Air,” by relocating the current stored diesel fuel oil and lube oil numerical volume requirements from the TS to a licensee controlled document. The TS would be modified so that the stored diesel fuel oil and lube oil inventory will require that a 7-day supply be available for each diesel generator. Condition A and Condition B in the Action table for TS 3.8.3 and Surveillance Requirements 3.8.3.1 and 3.8.3.2 would be revised to reflect the above change.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.
NRC Project Manager, Telephone Number	Michael Marshall, 301–415–2871.

PSEG Nuclear LLC; Hope Creek Generating Station; Salem County, NJ

Docket No(s)	50–354.
Application date	May 7, 2021.
ADAMS Accession No	ML21127A085.
Location in Application of NSHC	Pages 10–11 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendment would revise Technical Specification 3/4.7.1.3, “Ultimate Heat Sink” (UHS), to modify the limiting condition for operation river temperature, increase the temperature in the action statement for opening the emergency discharge valves, add a new 72-hour allowed outage time for one station service water system pump or one safety auxiliary cooling system pump or one emergency diesel generator inoperable with UHS temperature above 88 degrees Fahrenheit, and revise the UHS average temperature limit and maximum temperature.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Steven Fleischer, PSEG Services Corporation, 80 Park Plaza, T–5, Newark, NJ 07102.
NRC Project Manager, Telephone Number	James Kim, 301–415–4125.

Southern Nuclear Operating Company, Inc.; Edwin I Hatch Nuclear Plant, Units 1 and 2; Appling County, GA; Southern Nuclear Operating Company, Inc.; Joseph M Farley Nuclear Plant, Units 1 and 2; Houston County, AL; Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 1 and 2; Burke County, GA

Docket No(s)	50–321, 50–348, 50–364, 50–366, 50–424, 50–425.
Application date	June 22, 2021.
ADAMS Accession No	ML21173A064.
Location in Application of NSHC	Pages E–2 through E–4 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendments would revise the technical specifications to remove the table of contents from the Joseph M. Farley Nuclear Plant, Units 1 and 2; Edwin I. Hatch Nuclear Plant (Hatch), Units, 1 and 2; and Vogtle Electric Generating Plant, Units 1 and 2, as well as remove the effective page list from the Hatch, Units 1 and 2, technical specifications, to be put under the licensee’s control.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Millicent Ronnlund, Vice President and General Counsel, Southern Nuclear Operating Co., Inc., P. O. Box 1295, Birmingham, AL 35201–1295.
NRC Project Manager, Telephone Number	John Lamb, 301–415–3100.

Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 2; Rhea County, TN

Docket No(s)	50–391.
Application date	March 11, 2021.
ADAMS Accession No	ML21070A432.
Location in Application of NSHC	Pages E–5–E–7 of the Enclosure.
Brief Description of Amendment(s)	The proposed amendments would delete Watts Bar, Unit 2, technical specification (TS) requirements that will no longer apply following installation of the replacement steam generators (SGs) including: the F* SG tube inspection methodology, the voltage-based alternate repair criteria SG tube inspection methodology, and the provision allowing the use of SG tube sleeving as an SG tube repair methodology. The proposed amendment would also revise TS 5.7.2.12.d.2 to reflect the Technical Specifications Task Force (TSTF) Traveler TSTF–510, “Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection,” Revision 2, TS requirements for Alloy 690 thermally treated tubing that will apply to the replacement SGs. Lastly, the proposed amendment would revise Facility Operating License Condition 2.C.(4) to delete the reference to PAD4TCD, which will not apply to the replacement SGs.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	David Fountain, Executive VP and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 6A, Knoxville, TN 37902.
NRC Project Manager, Telephone Number	Kimberly Green, 301–415–1627.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last monthly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating

license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has

made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the table below. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

LICENSE AMENDMENT ISSUANCE(S)

DTE Electric Company; Fermi, Unit 2; Monroe County, MI

Docket No(s)	50-341.
Amendment Date	June 11, 2021.
ADAMS Accession No	ML21147A167.
Amendment No(s)	221.
Brief Description of Amendment(s)	The amendment revised the Fermi 2 technical specifications (TSs) to adopt Technical Specifications Task Force (TSTF) Traveler TSTF-563, Revision 0, "Revise Instrument Testing Definitions to Incorporate the Surveillance Frequency Control Program." Specifically, the amendment revised TS Section 1.1, "Definitions," to modify definitions for Channel Calibration and Channel Functional Test to allow the frequency for testing the components and devices in each step to be determined in accordance with the TS Surveillance Frequency Control Program.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Duke Energy Carolinas, LLC; Catawba Nuclear Station, Units 1 and 2; York County, SC; Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC

Docket No(s)	50-413, 50-414, 50-369, 50-370.
Amendment Date	June 23, 2021.
ADAMS Accession No	ML21131A026.
Amendment No(s)	Catawba—308 (Unit 1) and 304 (Unit 2); McGuire—318 (Unit 1) and 297 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Catawba Nuclear Station, Units 1 and 2 and McGuire Nuclear Station, Units 1 and 2 Technical Specification 3.8.1 regarding the emergency diesel generators to reduce the maximum steady state voltage specified in the associated surveillances.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Entergy Louisiana, LLC, and Entergy Operations, Inc.; River Bend Station, Unit 1; West Feliciana Parish, LA; Entergy Operations, Inc., System Energy Resources, Inc., Cooperative Energy, A Mississippi Electric Cooperative, and Entergy Mississippi, LLC; Grand Gulf Nuclear Station, Unit 1; Claiborne County, MS

Docket No(s)	50-416, 50-458.
Amendment Date	June 8, 2021.
ADAMS Accession No	ML21146A018.
Amendment No(s)	Grand Gulf—229 and River Bend—207.
Brief Description of Amendment(s)	The amendments changed the technical specifications to revise the current instrumentation testing definitions of Channel Calibration and Channel Functional Test to permit determination of the appropriate frequency to perform the surveillance requirement based on the devices being tested in each step. The changes are based on Technical Specifications Task Force (TSTF) Traveler TSTF-563, Revision 0, "Revise Instrument Testing Definitions to Incorporate the Surveillance Frequency Control Program."
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Entergy Nuclear Operations, Inc., Entergy Nuclear Indian Point 2, LLC; Indian Point Nuclear Generating Station, Unit No. 2; Westchester County, NY; Entergy Nuclear Operations, Inc., Entergy Nuclear Indian Point 3, LLC; Indian Point Nuclear Generating Station, Unit No. 3; Westchester County, NY; Entergy Nuclear Operations, Inc.; Indian Point Nuclear Generating Station, Unit No. 1; Westchester County, NY

Docket No(s)	50-003, 50-247, 50-286.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Amendment Date	May 28, 2021.
ADAMS Accession No	ML21126A004.
Amendment No(s)	64 (Unit 1), 295 (Unit 2), and 271 (Unit 3).
Brief Description of Amendment(s)	On November 23, 2020, the NRC issued an order approving the transfer of the licenses for Indian Point from Entergy to Holtec International (Holtec) subsidiaries, Holtec Indian Point 2, LLC and Holtec Indian Point 3, LLC. The order also approved the transfer of Entergy Nuclear Operations, Inc.'s (ENOI) operating authority for conducting license activities at the Indian Point Energy Center to Holtec Decommissioning International, LLC (HDI). The order also approved conforming administrative amendments to reflect the proposed transfer and to delete certain license conditions to reflect the satisfaction and termination of certain obligations after the license transfer. On May 28, 2021, Entergy and HDI informed the NRC that the transaction closed on May 28, 2021. Accordingly, the NRC issued Amendment No. 64 to Provisional License No. DPR-5, Amendment No. 295 to Renewed Facility License No. DPR-26, and Amendment No. 271 to Renewed Facility License No. DPR-64. A copy of the related Safety Evaluation (ADAMS Accession No. ML20297A333) was provided with the Order dated November 23, 2020, approving the license transfer and the conforming amendment.
Public Comments Received as to Proposed NSHC (Yes/No).	Yes.

Entergy Operations, Inc.; Waterford Steam Electric Station, Unit 3; St. Charles Parish, LA

Docket No(s)	50-382.
Amendment Date	May 19, 2021.
ADAMS Accession No	ML21082A302.
Amendment No(s)	259.
Brief Description of Amendment(s)	The amendment revised the current emergency action level scheme to one based on Nuclear Energy Institute (NEI) guidance in NEI 99-01, Revision 6, "Development of Emergency Action Levels for Non-Passive Reactors," dated November 2012, which was endorsed by the NRC in a letter dated March 26, 2013.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Exelon Generation Company, LLC; LaSalle County Station, Units 1 and 2; LaSalle County, IL

Docket No(s)	50-373, 50-374.
Amendment Date	May 27, 2021.
ADAMS Accession No	ML21082A422.
Amendment No(s)	249 (Unit 1) and 235 (Unit 2).
Brief Description of Amendment(s)	The amendments modified the licensing basis by the addition of a license condition to allow for the implementation of the provisions of 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors."
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Pacific Gas and Electric Company; Humboldt Bay Power Plant Unit 3; Humboldt County, CA

Docket No(s)	50-133.
Amendment Date	June 24, 2021.
ADAMS Accession No	ML21158A123.
Amendment Nos	46.
Brief Description of Amendment(s)	The amendment revised the Humboldt Bay Power Plant, Unit 3 (HBPP) license by revising License Condition 2.C.5. This license condition incorporates the revised License Termination Plan into the HBPP license. All other aspects of the license remain the same.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 2; Rhea County, TN

Docket No(s)	50-391.
Amendment Date	June 17, 2021.
ADAMS Accession No	ML21148A100.
Amendment No(s)	53.
Brief Description of Amendment(s)	The amendment revised Technical Specification 5.9.6, "Reactor Coolant System (RCS) Pressure and Temperature Limits Report (PTLR)," to add WCAP-18124-NP-A, Revision 0, "Fluence Determination with RAPTOR-M3G and FERRET," as a neutron fluence calculational methodology for the evaluation of reactor vessel specimens to support the determination of reactor coolant system pressure and temperature limits.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2; Somervell County, TX

Docket No(s)	50-445, 50-446.
Amendment Date	May 19, 2021.

LICENSE AMENDMENT ISSUANCE(S)—Continued

ADAMS Accession No	ML21061A217.
Amendment No(s)	180 (Unit 1) and 180 (Unit 2).
Brief Description of Amendment(s)	The amendments authorized changes and clarifications to specific emergency action levels of the Emergency Plan, and supporting bases discussions, for the Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2; Somervell County, TX	
Docket No(s)	50–445, 50–446.
Amendment Date	June 9, 2021.
ADAMS Accession No	ML21132A089.
Amendment No(s)	181 (Unit 1) and 181 (Unit 2).
Brief Description of Amendment(s)	The amendments adopted Technical Specifications Task Force (TSTF) Traveler TSTF–567, Revision 1, “Containment Sump TS [Technical Specification] to Address GSI [Generic Safety Issue]–191 Issues.” The amendments revised the TSs to address the condition of the containment sump made inoperable due to containment accident generated and transported debris exceeding the analyzed limits.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

IV. Notice of Issuance of Amendment to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Circumstances or Emergency Situation)

Since publication of the last monthly notice, the Commission has issued the following amendment. The Commission has determined for this amendment that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission’s rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission’s rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

Because of exigent circumstances or emergency situation associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed NSHC determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee’s facility of the licensee’s application and of the Commission’s proposed determination of NSHC. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of

communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant’s licensed power level, the Commission may not have had an opportunity to provide for public comment on its NSHC determination. In such case, the license amendment has been issued without opportunity for comment prior to issuance. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that NSHC is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendments involve NSHC. The basis for this determination is contained in the documents related to each action. Accordingly, the amendment has been issued and made effective as indicated. For those amendments that have not

been previously noticed in the **Federal Register**, within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the guidance concerning the Commission’s “Agency Rules of Practice and Procedure” in 10 CFR part 2 as discussed in section II.A of this document.

Unless otherwise indicated, the Commission has determined that the amendment satisfies the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for this amendment. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to these actions, see the amendment and associated documents such as the Commission’s letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the table below. The safety evaluation will provide the ADAMS accession number(s) for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the “Obtaining Information and Submitting Comments” section of this document.

LICENSE AMENDMENT ISSUANCE(S)—EXIGENT/EMERGENCY CIRCUMSTANCES

Exelon FitzPatrick, LLC and Exelon Generation Company, LLC; James A FitzPatrick Nuclear Power Plant; Oswego County, NY

Docket No(s)	50–333.
Amendment Date	June 14, 2021.
ADAMS Accession No	ML21162A042.
Amendment No(s)	342.
Brief Description of Amendment(s)	The amendment modified Technical Specification (TS) 3.5.1, “ECCS [Emergency Core Cooling System]—Operating,” Condition A; TS 3.6.4.1, “Secondary Containment,” Condition A; and TS 3.6.1.9 Residual Heat Removal (RHR) Containment Spray System,” as well as certain Surveillance Requirements to support emergent repair of the “A” RHR pump motor. Specifically, the amendment revised the completion time from 7 days to 34 days for the “A” RHR pump, the completion time from 4 hours to 30 hours for restoring secondary containment, and the completion time from 7 days to 27 days for restoring one containment spray subsystem to operable status. Additionally, the amendment allowed extending the completion of several surveillance requirements of equipment being protected during the replacement of the “A” RHR pump motor.
Local Media Notice (Yes/No)	No.
Public Comments Requested as to Proposed NSHC (Yes/No).	No.

V. Previously Published Notice of Consideration of Issuance of Amendment to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notice was previously published as separate individual notice.

It was published as an individual notice either because time did not allow the Commission to wait for this monthly notice or because the action involved exigent circumstances. It is repeated here because the monthly notice lists all amendments issued or proposed to be issued involving NSHC.

For details, including the applicable notice period, see the individual notice in the **Federal Register** on the day and page cited.

LICENSE AMENDMENT REQUEST(S)—REPEAT OF INDIVIDUAL **Federal Register** NOTICE**Exelon Generation Company, LLC; Braidwood Station, Units 1 and 2; Will County, IL**

Docket No(s)	50–456, 50–457.
Application Date	May 27, 2021.
ADAMS Accession No	ML21147A543.
Brief Description of Amendment(s)	The proposed amendment would revise Technical Specification Surveillance Requirement 3.7.9.2 to allow an ultimate heat sink temperature of less than or equal to 102.8 degrees Fahrenheit through September 30, 2021.
Date & Cite of Federal Register Individual Notice.	June 10, 2021 (86 FR 30991).
Expiration Dates for Public Comments & Hearing Requests.	July 12, 2021 (Public Comments); August 9, 2021 (Hearing Requests).

Dated: July 3, 2021.

For the Nuclear Regulatory Commission.

Jennifer L. Dixon-Herrity,
Acting Deputy, Director, Division of Operating
Reactor, Licensing, Office of Nuclear Reactor
Regulation.

[FR Doc. 2021–14642 Filed 7–12–21; 8:45 am]

BILLING CODE 7590–01–P

**NUCLEAR REGULATORY
COMMISSION**

[Docket Nos. 50–338 and 50–339; NRC–
2021–0123]

**Virginia Electric Power Company;
North Anna Power Station, Units 1 and
2**

AGENCY: Nuclear Regulatory
Commission.

ACTION: License amendment application; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License Nos. NPF–4 and NPF–7, issued to Virginia Electric Power Company (VEPCO), for operation of the North Anna Power Station, Units 1 and 2. The proposed amendment would add a new requirement to isolate Primary Grade water from the reactor coolant system within 1 hour following a reactor shutdown from Mode 2. Additionally, it would make an editorial change to Technical Specification (TS) 5.6.5, “Core Operating Limits Report (COLR).”

DATES: Submit comments by August 12, 2021. Request for a hearing or petitions for leave to intervene must be filed by September 13, 2021.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2021–0123. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–

A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Glenn E. Miller, Jr., Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2481, email: Ed.Miller@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0123, facility name, unit number(s), docket number(s), application date, and subject, if applicable, when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2021–0123.
- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at pdr.resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2021–0123 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. NPF–4; NPF–7, issued to VEPCO, for operation of the North Anna Power Station, Units 1 and 2, located in Louisa County, VA, in response to VEPCO’s application dated May 6, 2021 (ADAMS Accession No. ML21126A314).

The proposed amendment would add a new requirement to isolate Primary Grade water from the reactor coolant system within 1 hour following a reactor shutdown from Mode 2. Additionally, it would make an editorial change to TS 5.6.5, “Core Operating Limits Report (COLR).”

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC’s regulations.

The NRC has made a proposed determination that the license amendment request involves no significant hazards consideration (NSHC). Under the NRC’s regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of NSHC, which is presented below:

1. Does the proposed change involve a significant increase in the probability or

consequences of an accident previously evaluated?

Response: No.

There are no design changes associated with the proposed change. All design, material, and construction standards that were applicable prior to this amendment request will continue to be applicable. The proposed change will not affect accident initiators or precursors or alter the design, conditions, or configuration of the facility. The proposed change does not alter the way the plant is operated and maintained, with respect to accident initiators or precursors. [The proposed change] would allow for PG water isolation within 1 hour after entry into Mode 3 following reactor shutdown from Mode 2 when there is no planned dilution or makeup activity occurring. This would be an increase from the current Completion Time of 15 minutes. The 1-hour Completion Time following reactor shutdown is requested to continue to ensure prompt implementation of PG water isolation without placing an undue burden on the operating staff[.] Additionally, following a reactor shutdown, operators are highly focused on plant reactivity conditions and are now better equipped (since the reinsertion of SSAs at NAPS Units 1 and 2 in response to the lessons learned from the Surry Boron Dilution event in May 2011) to be able to identify, detect, and respond to reactivity changes that could be caused by an inadvertent dilution event. Additionally, an editorial change is made to TS 5.6.5, Core Operating Limits Report (COLR), to accurately reflect Amendments 287/270. Therefore, it is concluded that the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

There are no proposed design changes or changes in the methods by which any safety-related plant structures, systems, or components perform their specified safety functions. The proposed change will not affect the normal methods of plant operation or change any operating parameters. No equipment performance requirements will be affected. The proposed change will not alter any assumptions in the safety analyses. The proposed change does not involve a physical modification of the plant. No new accident scenarios, transient precursors, failure mechanisms, or limiting single failures will be introduced because of this proposed change. There will be no adverse effect or challenges imposed on any safety-related system because of this proposed change. Additionally, an editorial change is made to TS 5.6.5, Core Operating Limits Report (COLR), to accurately reflect Amendments 287/270. Therefore, it is concluded that the proposed amendment does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change would allow for PG water isolation within 1 hour after entry into

Mode 3 following reactor shutdown from Mode 2 when there is no planned dilution or makeup activity occurring. This would be a change from the current Completion Time of 15 minutes. The 1-hour Completion Time following reactor shutdown would ensure prompt implementation of PG water isolation without placing an undue burden on the operating staff and is consistent with prior NRC approved Completion Times for PG water isolation following reactor shutdown. There will be no effect on plant systems necessary to perform protection functions. No Instrument setpoints or system response times are affected and none of the acceptance criteria for any accident analysis will be changed. Consequently, the proposed change will have no impact on the radiological consequences of a design basis accident. Additionally, an editorial change is made to TS 5.6.5, Core Operating Limits Report (COLR), to accurately reflect Amendments 287/270. Therefore, it is concluded that the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the 3 standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves NSHC.

The NRC is seeking public comments on this proposed determination that the license amendment request involves NSHC. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 60-day notice period. However, if circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the

action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration, which will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 and on the NRC website at <https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as discussed below, is granted. Detailed guidance on electronic submissions is located in the Guidance for Electronic Submissions to the NRC (ADAMS Accession No. ML13031A056) and on the NRC website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system timestamps the document and sends the submitter an email

confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law

requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated May 6, 2021 (ADAMS Accession No. ML21126A314).

Attorney for licensee: William S. Blair, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar St., RS-2, Richmond, VA 23219.

NRC Branch Chief: Michael Markley.

Dated: July 7, 2021.

For the Nuclear Regulatory Commission.

Glenn E. Miller Jr.,

Senior Project Manager, Plant Licensing Branch II-1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021-14767 Filed 7-12-21; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket No. N2021-2; Order No. 5933]

Service Standard Changes

AGENCY: Postal Regulatory Commission.
ACTION: Notice.

SUMMARY: The Commission is revising the procedural schedule for the proposed service standard changes to First-Class Package Service. This notice informs the public of the revised procedural schedule.

DATES: *Discovery requests are due:* July 21, 2021; *Postal Service's answers to discovery are due:* July 28, 2021; *Notices confirming intent to conduct oral cross-examination are due:* July 28, 2021; *Requests to present oral argument are due:* July 28, 2021; *Notices of designations are due:* July 27, 2021; *Notices of designated materials are due:* July 30, 2021.

ADDRESSES: Submit filings electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit filings electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION: On June 17, 2021, the Postal Service filed a request for an advisory opinion

regarding planned changes to the service standards for First-Class Package Service.¹ On June 21, 2021, the Commission issued a notice and order concerning the Postal Service's request,² setting forth a procedural schedule for consideration of the planned changes. See Order No. 5920, Attachment 1.

On July 2, 2021, the Postal Service filed a notice of errata modifying certain pages of the Request and the supporting testimony filed on behalf of its three witnesses.³ The Postal Service also filed a notice revising the following supporting library references: USPS-LR-N2021-2-1, USPS-LR-N2021-2-4, USPS-LR-N2021-2-NP1, and USPS-LR-N2021-2-NP2.⁴ The Postal Service states that both sets of revisions are related to errors in how its summary tables were compiled and/or deficiencies in aggregating modeled results with unmodeled results. See Errata to Request and Testimony at 1-2.

In order to provide sufficient time for parties to analyze the implications of the modified data that were submitted following the Postal Service's initial filing, the Commission finds good cause to adjust the procedural schedule as described below and in the Attachment appearing below the signature of this Order. See 39 CFR 302.112(b).

The Commission previously set July 15, 2021 as the deadline for parties to file discovery requests regarding the Postal Service's direct case, and July 22, 2021 as the Postal Service's deadline to file answers to discovery requests. Order No. 5920 at 17. The deadline for parties to file discovery requests on the Postal Service's direct case has been changed to July 21, 2021, and the Postal Service's discovery answers must be filed by July 28, 2021.

The Commission previously set July 20, 2021 as the deadline for parties to file notices confirming intent to file a rebuttal case. *Id.* at 18. The deadline for parties to file these notices has been changed to July 23, 2021. The deadline to file a rebuttal case has been changed from July 29, 2021 to August 4, 2021. See *id.*

¹ United States Postal Service Request for an Advisory Opinion on Changes in the Nature of Postal Services, June 17, 2021 (Request).

² Notice and Order on the Postal Service's Request for an Advisory Opinion on Changes in the Nature of Postal Services, June 21, 2021 (Order No. 5920).

³ Notice of the United States Postal Service of Revisions to Certain Pages of the Request for an Advisory Opinion, USPS-T-1, USPS-T-2, and USPS-T-3—Errata, July 2, 2021 (Errata to Request and Testimony).

⁴ Notice of the United States Postal Service of Revisions to Library References 1, 4, NP1, and NP2—Errata, July 2, 2021.

The Commission also stated that, assuming no rebuttal case is filed, any party that intends to conduct oral cross-examination shall file a notice of intent to do so by July 22, 2021. *Id.* at 19. The deadline for parties to file notices of intent to conduct oral cross-examination has been changed to July 28, 2021. The previous deadline for Notices of Designations was set for July 23, 2021. *Id.* at 20. The deadline has been changed to July 27, 2021. The Postal Service was to file its Notice of Designated Materials by July 27, 2021. *Id.* The deadline for the Postal Service's Notice of Designated Materials has been changed to July 30, 2021.

The Commission previously set July 22, 2021 as the deadline for parties to request to present oral argument at the hearing, assuming no rebuttal case is filed. *Id.* at 22. This deadline has been changed to July 28, 2021.

Assuming no rebuttal case is filed, the Commission previously reserved July 29, 2021, July 30, 2021, and August 2, 2021 for hearing dates. *Id.* at 19. The

new reserved hearing dates shall be August 4–6, 2021.

Assuming no rebuttal case is filed, the deadline for initial briefs or statements of position was previously set for August 9, 2021 and reply briefs for August 16, 2021. *Id.* at 21. The new deadline for initial briefs and statements of position is August 13, 2021. The new deadline for reply briefs is August 20, 2021.

Additionally, the Commission also changes the dates previously reserved for hearing in the event of rebuttal and/or surrebuttal testimony as follows. If any party files a notice of intent to file a rebuttal case by July 23, 2021 but no surrebuttal testimony will be presented, then the new reserved hearing dates shall be August 11–13, 2021. If any party files a notice of intent to file a rebuttal case by July 23, 2021, and the Commission approves the presentation of surrebuttal testimony, then the new reserved hearing dates shall be August 18–20, 2021.

Motions for leave to file a surrebuttal case were due July 30, 2021 and

responses to these motions were due August 3, 2021. *Id.* at 18. These deadlines have been changed to August 6, 2021 and August 10, 2021, respectively. If granted, any surrebuttal case—previously due by August 5, 2021—is now due by August 11, 2021. *See id.*

The Commission shall issue its advisory opinion in this proceeding by September 29, 2021. The timing of the Commission's advisory opinion will still be completed prior to the Postal Service's announced plans to implement the changes no earlier than October 1, 2021. Request at 1.

It is ordered:

1. The modified procedural schedule for this proceeding is set forth below the signature of this order.

2. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,
Secretary.

PROCEDURAL SCHEDULE FOR DOCKET NO. N2021–2

[Modified by the Commission, July 8, 2021]

Discovery Deadlines for the Postal Service's Direct Case

Filing of Discovery Requests	July 21, 2021.
Filing of the Postal Service's Answers to Discovery	July 28, 2021.

Deadlines in Preparation for Hearing

Filing of Notice Confirming Intent to Conduct Oral Cross-Examination	July 28, 2021.
Filing of Request to Present Oral Argument	July 28, 2021.
Filing of Notice of Designations	July 27, 2021.
Filing of Notices of Designated Materials	July 30, 2021.

Rebuttal Case Deadlines (if applicable)

Filing of Notice Confirming Intent to File a Rebuttal Case	July 23, 2021.
Filing of Rebuttal Case	August 4, 2021.

Surrebuttal Case Deadlines (if applicable)

Filing of Motion for Leave to File Surrebuttal Case	August 6, 2021.
Filing of Response to Motion for Leave to File Surrebuttal Case	August 10, 2021.
Filing of Surrebuttal Case (if authorized)	August 11, 2021.

Hearing Dates

Hearings (with no Rebuttal Case)	August 4–6, 2021.
Hearings (with Rebuttal Case, but no authorized Surrebuttal Case)	August 11–13, 2021.
Hearings (with Rebuttal Case and authorized Surrebuttal Case)	August 18–20, 2021.

Briefing Deadlines

Filing of Initial Briefs (with no Rebuttal Case)	August 13, 2021.
Filing of Reply Briefs (with no Rebuttal Case)	August 20, 2021.

Statement of Position Deadline

Filing of Statement of Position (with no Rebuttal Case)	August 13, 2021.

Advisory Opinion Deadline

Filing of Advisory Opinion (absent determination of good cause for extension)	September 29, 2021.

[FR Doc. 2021-14859 Filed 7-12-21; 8:45 am]

BILLING CODE 7710-FW-P

POSTAL SERVICE**Transfer of Post Office Box Service in Selected Locations to the Competitive Product List****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service hereby provides notice that 227 locations will be reassigned from their market-dominant fee groups to competitive fee groups.

DATES: Effective date: August 29, 2021.

ADDRESSES: For additional information, please contact: Sheila Marano, Manager Product Management, Special Services, 475 L'Enfant Plaza SW, Room 2P836, Washington, DC 20260.

FOR FURTHER INFORMATION CONTACT: Valerie Pelton, 202-487-4341.

SUPPLEMENTARY INFORMATION: Locations providing Post Office Box service are classified as competitive or market dominant and assigned to fee groups based upon proximity to private sector competitors and other criteria. Competitive locations provide more services than market dominant ones and have somewhat higher fees.

In May 2011, the Postal Service filed a request with the Postal Regulatory Commission (PRC) to transfer approximately 6,800 PO Box locations from market-dominant to competitive fee groups, based on a showing that sufficient competition exists when a private sector alternative exists within five miles or less. PRC Docket No. MC2011-25. Documents pertinent to that proceeding are available at www.prc.gov, Docket No. MC2011-25. At that time, the Postal Service advised the PRC that a **Federal Register** notice

would be filed whenever the Postal Service subsequently updates the list of competitive locations by applying the criteria approved in that docket. Since the original filing, the Postal Service updated the list of competitive locations in 2013 to add an additional location, *see* 79 FR 60928-60929 (Oct. 2, 2013), and subsequently updated it again to add 1625 locations effective Aug. 27, 2014, *see* 79 FR 38972-38998 (July 9, 2014). Competitive Post Office Box service includes several enhancements such as: electronic notification of the receipt of mail, use of an alternate street address format, signature on file for delivery of certain accountable mail, and additional hours of access and/or earlier availability of mail in some locations.

On May 11, 2021, the Postal Service provided notice with opportunity to comment of its re-application of the Docket No. MC2011-25 criteria to 237 PO Box locations (out of a total of approximately 32,788 locations). The Postal Service has not received any comments. Accordingly, the Postal Service hereby provides notice that Post Office® Box service for the 227 ZIP Code® locations listed below is reassigned from market dominant fee groups to competitive fee groups effective August 29, 2021.

This Notice also updates the May 11 list to exclude 10 locations which were erroneously included as those locations are for contract postal units (CPUs). The updated list of 227 PO Box locations are properly classified as competitive based on their proximity to a private sector competitor within five miles. The Postal Service updated the list of locations to remove the 10 CPU locations and confirms that the 227 reclassified locations meet all of the criteria that the Commission considered in Docket No. MC2011-25. The Postal Service used WebBATS and geospatial data to identify and confirm that each post

office location is within five miles of a private sector competitor. The Postal Service excluded locations with less than 250 boxes due to the “small customer base” and locations with access constraints.

Communications are being sent to the identified Postmasters of the locations; and PO Box customers in the identified 227 Post Office locations will receive an email and/or letter notifying them that their PO Boxes are now competitive locations and include the additional services. Additional internal and external communications will be sent as well. A list of affected locations, with the associated ZIP Codes, is provided in the Appendix to this notice. No comments were received or delivered by mail with the initial notice.

Joshua Hofer,

Attorney, Ethics & Legal Compliance.

Appendix—Transfer of Additional Post Office Box Locations to Competitive Fee Group—ZIP Code Listing

The following is a list of the locations which are described in the Notice above reassigned from market dominant to competitive fee groups. The list is sorted by ZIP Code in ascending numerical order with geographical breaks and headers. As indicated by the column headings, this list provides the ZIP Code of the affected PO Boxes (ZIP), the office name of the location (OFFICE NAME), the city where the PO Boxes are located (CITY), the current market dominant fee group (CFG), and the new competitive fee group (NFG). Please note that there are more ZIP Codes than locations being moved to competitive fee groups, because some locations serve more than one ZIP Code. These locations can be identified whenever multiple ZIP Codes are listed for a single office name.

The list of 227 transferred locations is below.

ZIP	Facilities name	City	St	CFG	NFG
ALABAMA					
35010	ALEXANDER CITY	ALEXANDER CITY	AL	4	34
35044	CHILDERSBURG	CHILDERSBURG	AL	4	34
35453	COTTONDALE	COTTONDALE	AL	5	35
35068	FULTONDALE	FULTONDALE	AL	5	35
35071	GARDENDALE	GARDENDALE	AL	5	35
35094	LEEDS	LEEDS	AL	4	34
36303	NORTHSIDE	DOTHAN	AL	4	34
35179	VINEMONT	VINEMONT	AL	5	35
ARKANSAS					
72501	BATESVILLE	BATESVILLE	AR	5	35
72543	HEBER SPRINGS	HEBER SPRINGS	AR	5	35

ZIP	Facilities name	City	St	CFG	NFG
ARIZONA					
85321	AJO	AJO	AZ	3	33
86323	CHINO VALLEY	CHINO VALLEY	AZ	5	35
85356	WELLTON	WELLTON	AZ	4	34
CALIFORNIA					
95225	BURSON	BURSON	CA	4	34
93210	COALINGA	COALINGA	CA	5	35
95426	COBB	COBB	CA	5	35
92242	EARP	EARP	CA	3	33
92548	HOMELAND	HOMELAND	CA	4	34
92251	IMPERIAL	IMPERIAL	CA	3	33
95454	LAYTONVILLE	LAYTONVILLE	CA	5	35
94305	STANFORD	STANFORD	CA	3	33
92277	TWENTYNINE PALMS	TWENTYNINE PALMS	CA	2	32
96093	WEAVERVILLE	WEAVERVILLE	CA	5	35
COLORADO					
80102	BENNETT	BENNETT	CO	6	36
81211	BUENA VISTA	BUENA VISTA	CO	4	34
80701	FORT MORGAN	FORT MORGAN	CO	4	34
CONNECTICUT					
06268	STORRS MANSFIELD	STORRS MANSFIELD	CT	3	33
FLORIDA					
32615	ALACHUA	ALACHUA	FL	4	34
34420	BELLEVIEW	BELLEVIEW	FL	5	35
33043	BIG PINE KEY	BIG PINE KEY	FL	5	35
32131	EAST PALATKA	EAST PALATKA	FL	4	34
32439	FREEPORT	FREEPORT	FL	3	33
32040	GLEN SAINT MARY	GLEN SAINT MARY	FL	5	35
34736	GROVELAND	GROVELAND	FL	4	34
32063	MACCLENNEY	MACCLENNEY	FL	3	33
34753	MASCOTTE	MASCOTTE	FL	7	37
34762	OKAHUMPKA	OKAHUMPKA	FL	7	37
32177	PALATKA	PALATKA	FL	4	34
34219	PARRISH	PARRISH	FL	4	34
33946	PLACIDA	PLACIDA	FL	5	35
33570	RUSKIN	RUSKIN	FL	4	34
33957	SANIBEL	SANIBEL	FL	5	35
32959	SHARPES	SHARPES	FL	5	35
33873	WAUCHULA	WAUCHULA	FL	5	35
32362	WOODVILLE	WOODVILLE	FL	4	34
33890	ZOLFO SPRINGS	ZOLFO SPRINGS	FL	5	35
GEORGIA					
30553	LAVONIA	LAVONIA	GA	4	34
31757	TALL TIMBERS VLG	THOMASVILLE	GA	4	34
30474	VIDALIA	VIDALIA	GA	4	34
30680	WINDER	WINDER	GA	4	34
GUAM					
96929	ANDERSEN AFB	YIGO	GU	1	31
96913	BARRIGADA	BARRIGADA	GU	1	31
96910	HAGATNA	HAGATNA	GU	1	31
HAWAII					
96719	HAWI	HAWI	HI	3	33
IOWA					
50125	INDIANOLA	INDIANOLA	IA	5	35
52501	OTTUMWA	OTTUMWA	IA	5	35

ZIP	Facilities name	City	St	CFG	NFG
IDAHO					
83853	PORTHILL	PORTHILL	ID	5	35
83467	SALMON	SALMON	ID	3	33
ILLINOIS					
60115	DEKALB	DEKALB	IL	5	35
61801	DOWNTOWN URBANA	URBANA	IL	3	33
60099	ZION	ZION	IL	4	34
INDIANA					
46312	EAST CHICAGO	EAST CHICAGO	IN	4	34
46140	GREENFIELD	GREENFIELD	IN	3	33
46320	HAMMOND	HAMMOND	IN	2	32
KANSAS					
67601	HAYS	HAYS	KS	4	34
66618	NORTHPARK	TOPEKA	KS	4	34
KENTUCKY					
42330	CENTRAL CITY	CENTRAL CITY	KY	4	34
41635	HAROLD	HAROLD	KY	5	35
42431	MADISONVILLE	MADISONVILLE	KY	4	34
40165	SHEPHERDSVILLE	SHEPHERDSVILLE	KY	7	37
LOUISIANA					
71405	BALL	BALL	LA	5	35
70427	BOGALUSA	BOGALUSA	LA	4	34
70043	CHALMETTE	CHALMETTE	LA	6	36
70359	GRAY	GRAY	LA	5	35
71360	PINEVILLE	PINEVILLE	LA	3	33
70663	SULPHUR	SULPHUR	LA	4	34
71477	TIOGA	TIOGA	LA	5	35
MARYLAND					
20613	BRANDYWINE	BRANDYWINE	MD	4	34
20755	FORT GEORGE G MEADE	FORT GEORGE G MEADE	MD	3	33
MAINE					
04619	CALAIS	CALAIS	ME	2	32
04543	DAMARISCOTTA	DAMARISCOTTA	ME	4	34
04043	KENNEBUNK	KENNEBUNK	ME	1	31
04046	KENNEBUNKPORT	KENNEBUNKPORT	ME	4	34
04758	MARS HILL	MARS HILL	ME	3	33
04553	NEWCASTLE	NEWCASTLE	ME	4	34
04094	WEST KENNEBUNK	WEST KENNEBUNK	ME	4	34
MICHIGAN					
49401	ALLENDALE	ALLENDALE	MI	5	35
48111	BELLEVILLE	BELLEVILLE	MI	5	35
49306	BELMONT	BELMONT	MI	5	35
MINNESOTA					
56537	FERGUS FALLS	FERGUS FALLS	MN	4	34
56001	MANKATO	MANKATO	MN	3	33
MISSOURI					
63841	DEXTER	DEXTER	MO	5	35
64083	RAYMORE	RAYMORE	MO	3	33
63117	RICHMOND HEIGHTS	SAINT LOUIS	MO	2	32
63080	SULLIVAN	SULLIVAN	MO	3	33
MISSISSIPPI					
39342	MARION	MARION	MS	6	36

ZIP	Facilities name	City	St	CFG	NFG
39305	NORTH MERIDIAN	MERIDIAN	MS	4	34
39307	WEST MERIDIAN	MERIDIAN	MS	4	34
MONTANA					
59917	EUREKA	EUREKA	MT	4	34
59752	THREE FORKS	THREE FORKS	MT	4	34
NORTH CAROLINA					
28725	DILLSBORO	DILLSBORO	NC	5	35
27244	ELON	ELON	NC	5	35
28307	FORT BRAGG	FORT BRAGG	NC	2	32
28741	HIGHLANDS	HIGHLANDS	NC	5	35
28348	HOPE MILLS	HOPE MILLS	NC	2	32
27021	KING	KING	NC	5	35
28645	LENOIR	LENOIR	NC	3	33
27557	MIDDLESEX	MIDDLESEX	NC	5	35
27030	MOUNT AIRY	MOUNT AIRY	NC	3	33
28372	PEMBROKE	PEMBROKE	NC	5	35
27045	RURAL HALL	RURAL HALL	NC	5	35
28779	SYLVA	SYLVA	NC	3	33
27049	TOAST	TOAST	NC	5	35
28788	WEBSTER	WEBSTER	NC	5	35
NORTH DAKOTA					
58784	STANLEY	STANLEY	ND	5	35
NEBRASKA					
69341	GERING	GERING	NE	4	34
69361	SCOTTSBLUFF	SCOTTSBLUFF	NE	4	34
NEW HAMPSHIRE					
03253	MEREDITH	MEREDITH	NH	5	35
NEW JERSEY					
07001	AVENEL	AVENEL	NJ	1	31
08002	ELLISBURG	CHERRY HILL	NJ	3	33
07630	EMERSON	EMERSON	NJ	1	31
NEW MEXICO					
87015	EDGEWOOD	EDGEWOOD	NM	5	35
88047	MESILLA PARK	MESILLA PARK	NM	4	34
NEVADA					
89883	WEST WENDOVER	WEST WENDOVER	NV	5	35
89445	WINNEMUCCA	WINNEMUCCA	NV	3	33
NEW YORK					
13502	BUTTERFIELD	UTICA	NY	4	34
12919	CHAMPLAIN	CHAMPLAIN	NY	5	35
12920	CHATEAUGAY	CHATEAUGAY	NY	5	35
13640	FINEVIEW	WELLESLEY ISLAND	NY	4	34
13602	FORT DRUM	FORT DRUM	NY	3	33
13655	HOGANSBURG	HOGANSBURG	NY	5	35
14843	HORNELL	HORNELL	NY	3	33
14845	HORSEHEADS	HORSEHEADS	NY	3	33
13501	KERNAN	UTICA	NY	4	34
13403	MARCY	MARCY	NY	5	35
13662	MASSENA	MASSENA	NY	4	34
13413	NEW HARTFORD	NEW HARTFORD	NY	3	33
13440	ROME	ROME	NY	4	34
13683	ROOSEVELTOWN	ROOSEVELTOWN	NY	5	35
13504	UTICA	UTICA	NY	4	34
OHIO					
43062	PATASKALA	PATASKALA	OH	4	34

ZIP	Facilities name	City	St	CFG	NFG
44907	SOUTHWEST	MANSFIELD	OH	4	34
44281	WADSWORTH	WADSWORTH	OH	3	33
OKLAHOMA					
74429	COWETA	COWETA	OK	3	33
73533	DUNCAN	DUNCAN	OK	4	34
74554	KREBS	KREBS	OK	5	35
74501	MCALISTER	MCALISTER	OK	4	34
73801	WOODWARD	WOODWARD	OK	4	34
OREGON					
97325	AUMSVILLE	AUMSVILLE	OR	5	35
97814	BAKER CITY	BAKER CITY	OR	3	33
97523	CAVE JUNCTION	CAVE JUNCTION	OR	4	34
97351	INDEPENDENCE	INDEPENDENCE	OR	3	33
97361	MONMOUTH	MONMOUTH	OR	3	33
97381	SILVERTON	SILVERTON	OR	4	34
97385	SUBLIMITY	SUBLIMITY	OR	4	34
PENNSYLVANIA					
19023	DARBY	DARBY	PA	3	33
19348	KENNETT SQUARE	KENNETT SQUARE	PA	3	33
17044	LEWISTOWN	LEWISTOWN	PA	4	34
17850	MONTANDON	MONTANDON	PA	5	35
18015	SOUTHSIDE	BETHLEHEM	PA	3	33
19372	THORNDALE	THORNDALE	PA	3	33
18657	TUNKHANNOCK	TUNKHANNOCK	PA	3	33
19375	UNIONVILLE	UNIONVILLE	PA	5	35
PUERTO RICO					
00936	SAN JUAN	SAN JUAN	PR	2	32
00976	TRUJILLO ALTO	TRUJILLO ALTO	PR	2	32
RHODE ISLAND					
02882	NARRAGANSETT	NARRAGANSETT	RI	2	32
SOUTH CAROLINA					
29822	CLEARWATER	CLEARWATER	SC	5	35
29569	LORIS	LORIS	SC	3	33
SOUTH DAKOTA					
57532	FORT PIERRE	FORT PIERRE	SD	6	36
57501	PIERRE	PIERRE	SD	5	35
57069	VERMILLION	VERMILLION	SD	4	34
57078	YANKTON	YANKTON	SD	4	34
TENNESSEE					
37643	ELIZABETHTON	ELIZABETHTON	TN	3	33
37062	FAIRVIEW	FAIRVIEW	TN	5	35
37743	GREENEVILLE	GREENEVILLE	TN	3	33
TEXAS					
75751	ATHENS	ATHENS	TX	3	33
75551	ATLANTA	ATLANTA	TX	5	35
78133	CANYON LAKE	CANYON LAKE	TX	5	35
78834	CARRIZO SPRINGS	CARRIZO SPRINGS	TX	7	37
78234	FORT SAM HOUSTON	JB SA FT SAM HOUSTON	TX	5	35
78358	FULTON	FULTON	TX	6	36
78026	JOURDANTON	JOURDANTON	TX	4	34
75142	KAUFMAN	KAUFMAN	TX	3	33
79331	LAMESA	LAMESA	TX	5	35
78642	LIBERTY HILL	LIBERTY HILL	TX	7	37
77864	MADISONVILLE	MADISONVILLE	TX	4	34
77357	NEW CANEY	NEW CANEY	TX	6	36
77630	ORANGE	ORANGE	TX	5	35
77446	PRAIRIE VIEW	PRAIRIE VIEW	TX	7	37

ZIP	Facilities name	City	St	CFG	NFG
75572	QUEEN CITY	QUEEN CITY	TX	6	36
77510	SANTA FE	SANTA FE	TX	7	37
79556	SWEETWATER	SWEETWATER	TX	5	35
76692	WHITNEY	WHITNEY	TX	7	37
75169	WILLS POINT	WILLS POINT	TX	4	34
UTAH					
84651	PAYSON	PAYSON	UT	4	34
VIRGINIA					
20143	CATHARPIN	CATHARPIN	VA	5	35
24504	COURTHOUSE LYNCHBURG	LYNCHBURG	VA	3	33
23801	FORT LEE	FORT LEE	VA	3	33
22630	FRONT ROYAL	FRONT ROYAL	VA	3	33
24572	MADISON HEIGHTS	MADISON HEIGHTS	VA	5	35
VIRGIN ISLANDS					
00802	CHARLOTTE AMALIE	ST THOMAS	VI	2	32
00830	CRUZ BAY	ST JOHN	VI	5	35
00802	EMANCIPATION GARDENS	ST THOMAS	VI	2	32
00802	VETERANS ANNEX	ST THOMAS	VI	3	33
VERMONT					
05440	ALBURGH	ALBURGH	VT	4	34
05033	BRADFORD	BRADFORD	VT	4	34
05830	DERBY LINE	DERBY LINE	VT	5	35
05855	NEWPORT	NEWPORT	VT	3	33
05478	SAINT ALBANS	SAINT ALBANS	VT	3	33
05676	WATERBURY	WATERBURY	VT	2	32
05777	WEST RUTLAND	WEST RUTLAND	VT	4	34
WASHINGTON					
99109	CHEWELAH	CHEWELAH	WA	5	35
99006	DEER PARK	DEER PARK	WA	5	35
98257	LA CONNER	LA CONNER	WA	5	35
98045	NORTH BEND	NORTH BEND	WA	4	34
98844	OROVILLE	OROVILLE	WA	5	35
98394	VAUGHN	VAUGHN	WA	3	33
WISCONSIN					
53029	HARTLAND	HARTLAND	WI	4	34
54476	SCHOFIELD	SCHOFIELD	WI	3	33
54880	SUPERIOR	SUPERIOR	WI	4	34
WEST VIRGINIA					
26330	BRIDGEPORT	BRIDGEPORT	WV	4	34
25625	HOLDEN	HOLDEN	WV	5	35
24901	LEWISBURG	LEWISBURG	WV	4	34
25560	SCOTT DEPOT	SCOTT DEPOT	WV	5	35
25652	WHITMAN	WHITMAN	WV	5	35
WYOMING					
82716	GILLETTE	GILLETTE	WY	5	35
82072	LARAMIE	LARAMIE	WY	5	35

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92337; No. SR-NYSEArca-2021-58]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

July 7, 2021.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the “Act”)² and Rule 19b-4 thereunder,³ notice is hereby given that, on July 1, 2021, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (“Fee Schedule”) regarding incentive programs offered by the Exchange. The Exchange proposes to implement the fee change effective July 1, 2021. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to make modifications to one of the Customer Posting Credit Tiers in Non-Penny Issues and to introduce an additional Discount in Take Liquidity Fees for Professional Customers and Non-Customer Liquidity Removing Interest, as described below. The Exchange proposes to implement the fee change effective July 1, 2021.

Customer Posting Credit Tiers in Non-Penny Issues (the “Non-Penny Tiers”)

The Non-Penny Tiers provide that OTP Holders and OTP Firms (“OTP Holders”) can qualify for per contract credits applied to electronic options transactions based on meeting certain minimum volume thresholds from Customer posting interest in non-Penny issues. The Exchange proposes to modify the Non-Penny Tiers by providing an alternative qualification method to achieve Non-Penny Tier F.

The proposed alternative qualification for Non-Penny Tier F would offer the same (\$1.02) per contract credit and would be available to OTP Holders that execute at least 2.00% of Total Industry Customer equity and ETF option average daily volume (“TCADV”)⁴ from Customer posted interest in all issues and at least 2.00% of TCADV from Professional Customer and Non-Customer Liquidity Removing interest in all issues.⁵

The proposed alternative qualification to achieve Non-Penny Tier F is designed to continue to attract Customer order flow for all issues to the Exchange and also to reward posted liquidity, which provides benefits to all market participants by providing more trading opportunities, which in turn attracts Customers, Market Makers, and other Non-Customer interest. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

Notwithstanding the proposed change to Non-Penny Tier F, OTP Holders are still eligible to qualify for the Non-

Penny Tier F per contract credit of (\$1.02) under the alternative (and unchanged) threshold, which requires that an OTP Holder execute at least 1.00% of TCADV from Customer posted interest in all issues, plus executed ADV of 0.30% of U.S. Equity Market Share Posted and Executed on NYSE Arca Equity Market to achieve the (\$1.02) per contract credit. By continuing to provide such alternative methods to qualify for a Non-Penny Tier, the Exchange believes the opportunities to qualify for credits is increased, which benefits all participants through increased volume to the Exchange.

Discount in Take Liquidity Fees for Professional Customers and Non-Customer Liquidity Removing Interest (Each a “Take Fee Discount”)

If an OTP Holder executes a transaction that removes or “takes” liquidity on the Exchange, the OTP Holder is charged a “Take Liquidity” fee (referred to herein as “Take Fees”) and such liquidity may be referred to as “Liquidity Removing” or liquidity taking.⁶ To offset such costs and to encourage market participants to direct order flow to the Exchange, the Exchange offers, among other incentives, the Take Fee Discounts for executions in Penny Issues.⁷

The Exchange proposes to add an additional means of qualifying for a Take Fee Discount for executions in Penny Issues. As proposed, the Exchange would offer a new Take Fee Discount, which would provide an additional \$0.03 per contract discount on Take Fees for OTP Holders that executed at least 2.00% of TCADV from Customer posted interest in all issues and at least 2.00% of TCADV from Professional Customer and Non-Customer Liquidity Removing interest in all issues. The Exchange also proposes to add text to the Fee Schedule making clear that only one of the three alternative Take Fee Discounts for executions in Penny Issues would apply to an OTP Holder’s activities.

The Exchange believes this proposed change would incent OTP Holders to increase the amount of Customer posted volume executed on the Exchange

⁶ See Fee Schedule, NYSE Arca OPTIONS: TRADE-RELATED CHARGES FOR STANDARD OPTIONS, TRANSACTION FEE FOR ELECTRONIC EXECUTIONS-PER CONTRACT (setting forth a per contract Take Fee of \$1.10 for such non-Penny executions in Professional Customer, Firm, Broker Dealer, and Market Maker range as compared to a per contract take fee of \$0.85 for such non-Penny executions in the Customer range).

⁷ The Exchange is not proposing to modify the (single) Take Fee Discount available to OTP Holders that achieve the minimum volume executions in non-Penny Issues.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ See Fee Schedule, Endnote 8 (providing that TCADV “includes OCC calculated Customer volume of all types, including Complex Order Transactions and QCC transactions, in equity and ETF options”).

⁵ “Non-Customer” interest on the Exchange includes interest from Firms, Broker Dealers, and Market Makers. See Fee Schedule, NYSE Arca OPTIONS: TRADE-RELATED CHARGES FOR STANDARD OPTIONS (preamble).

(while maintaining the same level of Liquidity Removing volume required under one of the existing Take Fee Discounts), which activity may result in tighter spreads and more trading making the Exchange a more attractive trading venue to the benefit of all participants.⁸

The proposed new Take Fee Discount is designed to attract additional Customer order flow and to continue to attract a broad spectrum of liquidity-taking volume, which provides benefits for all market participants by providing more trading opportunities, which attracts Customers, Market Makers, and other Non-Customer interest. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Exchange believes this proposed Take Fee Discount would encourage OTP Holders to achieve this additional discount with increased activity from a variety of business interest. By providing an incentive for take liquidity activity, the Exchange in turn provides more opportunities for execution of posted interest.

The Exchange notes that an OTP Holder that qualifies for the new alternative volume threshold under Non-Penny Tier F would also qualify for the new Take Fee Discount, as both incentives consist of the same minimum volume threshold and the same mix of business activity. The Exchange notes that new Take Fee Discount does not apply to credits associated with the Non-Penny Tiers, and is designed to encourage OTP Holders to direct a variety of business to the Exchange, including liquidity-taking business, which in turn encourages posted interest. To the extent that the proposed incentives operate as intended, the anticipated result would be that the Exchange would be a more attractive execution venue for all options business.

Notwithstanding the proposed new Take Fee Discount, the Exchange notes that OTP Holders are still eligible to qualify for the existing alternative (and unchanged) Take Fee Discounts for executions in Penny Issues. By continuing to provide such alternative methods to qualify for Take Fee Discounts, the Exchange believes the opportunities to qualify for credits is increased, which benefits all

participants through increased volume to the Exchange.

The Exchange cannot predict with certainty whether any OTP Holders will avail themselves of the proposed changes to the Non-Penny Tiers or Take Fee Discounts. At present, whether or when an OTP Holder would qualify for the enhanced credit varies month-to-month. Thus, the Exchange cannot predict with any certainty the number of OTP Holders that may qualify for the proposed new qualifications, but believes that OTP Holders would be encouraged to increase volume to take advantage of the proposed incentive credits/discounts.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,¹⁰ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹¹

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹² Therefore, currently no exchange possesses significant pricing power in

the execution of multiply-listed equity & ETF options order flow. More specifically, in May 2021, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹³

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. In response to this competitive environment, the Exchange has established incentives, such as the Non-Penny Tiers and the Take Fee Discount.

The Exchange believes that the proposed modification to the Non-Penny Tier F—to provide an alternative qualification basis through a mix of Customer posted interest and Professional Customer and Non-Customer liquidity-taking interest—is reasonably designed to continue to incent OTP Holders to increase the amount and type of Customer interest sent and to also to reward posted liquidity. An increase in Customer volume would create more trading opportunities, which, in turn attracts Market Makers. A resulting increase in Market-Maker activity may facilitate tighter spreads, which may lead to an additional increase of order flow from other market participants, further contributing to a deeper, more liquid market to the benefit of all market participants by creating a more robust and well-balanced market ecosystem. With regard to Professional Customer and Non-Customer liquidity-taking interest, the Exchange believes that the proposed Tier F is reasonably designed to incent OTP Holders to increase trading activity in all issues and in a variety of account types on the Exchange, which increased liquidity benefits all market participants because of increased trading opportunities and price discovery. Moreover, to the extent that the proposed change to Non-Penny Tier F results in an increase in both posted Customer interest and Professional Customer and Non-Customer liquidity-taking interest, this increased volume benefits all market participants as it may result in tighter spreads and more trading making the Exchange a more attractive trading venue to the benefit of all participants.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(4) and (5).

¹¹ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (“Reg NMS Adopting Release”).

¹² The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics>.

¹³ Based on OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, *see id.*, the Exchange’s market share in equity-based options decreased from 11.17% for the month of May 2020 to 9.28% for the month of May 2021.

⁸ The Exchange notes that it currently offers a \$0.02 per contract Take Fee Discount for executions in Penny Issues provided an OTP Holder execute at least 1.00% TCADV from Customer posted interest in all issues OR at least 2.00% of TCADV from Professional Customer and Non-Customer Liquidity Removing interest in all issues.

The proposed new Take Fee Discount has a minimum volume threshold identical to proposed threshold required under new Non-Penny Tier F and similarly includes a take liquidity volume requirement. As stated before, this discount is reasonably designed to increase the amount and type of Professional Customer and Non-Customer interest sent to the Exchange, especially posted and liquidity-taking interest, which benefits all market participants by providing more trading opportunities, which attracts Customers, Market Makers, and Non-Customer interest. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Exchange believes that this proposed new Take Fee Discount would encourage OTP Holders to achieve the alternative discount with trading activity from a variety of market participants, which would make the Exchange a more attractive execution venue.

To the extent the proposed rule change continues to attract greater volume and liquidity by encouraging OTP Holders (and their affiliates) to increase their options volume on the Exchange in an effort to achieve credits through the Non-Penny Tiers as well as the Take Fee Discount, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors.

The proposed additional text to the Take Fee discount making clear that only one of the three Take Fee Discounts (for executions in Penny Issues) is available to OTP Holders is reasonably designed to add clarity and transparency to the Fee Schedule making it easier to navigate and comprehend.

The Proposed Rule Change is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposal is based on the amount and type of business transacted on the Exchange and OTP Holders can opt to avail themselves of the credits and discounts or not. Moreover, the proposal is designed to incent OTP Holders to aggregate all Customer posting interest

and Professional Customer and Non-Customer Take Liquidity interest at the Exchange as a primary execution venue. To the extent that the proposed change attracts more Customer posting interest and more Professional Customer and Non-Customer liquidity-taking interest, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed modifications to the Non-Penny Tier F and the Take Fee Discount are not unfairly discriminatory because the proposed modifications would be available to all similarly-situated market participants on an equal and non-discriminatory basis.

The proposal is based on the amount and type of business transacted on the Exchange and OTP Holders are not obligated to try to achieve the proposed qualification basis for Non-Penny Tier F or the new Take Fee Discount, nor are OTP Holders obligated to execute posted interest. Rather, the proposal is designed to encourage OTP Holders to utilize the Exchange as a primary trading venue (if they have not done so previously) for both Customer posted interest and liquidity-taking interest from Professional Customers and Non-Customers. To the extent that the proposed change attracts more Customer interest, including posted and liquidity-taking interest to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, 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.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the

Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."¹⁴

Intramarket Competition. The proposed change is designed to attract additional order flow (particularly Customer posted interest and Professional Customer and Non-Customer liquidity-taking interest) to the Exchange. The Exchange believes that the proposed modification to Non-Penny Tier F and the new Take Fee Discount would incent OTP Holders to direct their Customer order flow and their take liquidity order flow from other market participants to the Exchange. Greater liquidity benefits all market participants on the Exchange and increased Customer order flow and Professional Customer and Non-Customer liquidity-taking interest would increase opportunities for execution of other trading interest. The proposed modifications to Non-Penny Tier F and the new Take Fee Discount would be available to all similarly-situated market participants that execute electronic Customer posted interest and Professional Customer and Non-Customer liquidity-taking interest, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its

¹⁴ See Reg NMS Adopting Release, *supra* note 11, at 37499.

fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹⁵ Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in May 2021, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.¹⁶

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees and credits in a manner that is competitive and designed to incent OTP Holders to direct trading interest (particularly Customer posted interest and Professional Customer and Non-Customer liquidity-taking interest) to the Exchange, to provide liquidity and to attract order flow. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues as OTP Holders (and their affiliates) may direct their order flow to any of the 16 options exchanges, including those that offer similar pricing incentives and discounts. The Exchange also believes that the proposed change is designed to provide the public and investors with a Fee Schedule that is clear and consistent, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section

19(b)(3)(A)¹⁷ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁸ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁹ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2021-58 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-NYSEArca-2021-58. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and

printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2021-58, and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-14794 Filed 7-12-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92341; File No. SR-FICC-2021-004]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change Relating to Confidential Information, Market Disruption Events, and Other Changes

July 7, 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 June 25, 2021, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. 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 proposed rule change consists of modifications to FICC's Government Securities Division ("GSD") Rulebook (the "GSD Rules"), Mortgage-Backed Securities Division ("MBSD") Clearing Rules (the "MBSD Clearing Rules") and

¹⁵ See *supra* note 12.

¹⁶ Based on OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, see *id.*, the Exchange's market share in equity-based options decreased from 11.17% for the month of May 2020 to 9.28% for the month of May 2021.

¹⁷ 15 U.S.C. 78s(b)(3)(A).

¹⁸ 17 CFR 240.19b-4(f)(2).

¹⁹ 15 U.S.C. 78s(b)(2)(B).

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

MBSD EPN Rules (the “EPN Rules,” and collectively with the GSD Rules and the MBSD Clearing Rules, the “Rules”)³ to (i) revise certain provisions in the Rules relating to the confidentiality of information furnished by applicants, Members and EPN Users (collectively, “participants”) to FICC, (ii) require that each participant maintain confidential information furnished by FICC or its affiliates in confidence and restrict use and disclosure of such information, (iii) add certain officers who are allowed to determine that there is a Market Disruption Event pursuant to GSD Rule 50 and MBSD Rule 40 and (iv) add a new GSD Rule 50A and MBSD Rule 40A to address situations in which it is necessary to disconnect a Member, EPN User, third party service provider, or service bureau due to an imminent threat of harm to FICC, Members, EPN Users and/or other market participants. Each of the proposed changes is described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The proposed rule change consists of modifications to (i) revise certain provisions in the Rules relating to the confidentiality of information furnished by participants to FICC, (ii) require that each participant maintain confidential information furnished by FICC or its affiliates in confidence and restrict use and disclosure of such information, (iii) add certain officers who are allowed to determine that there is a Market Disruption Event pursuant to GSD Rule 50 and MBSD Rule 40 and (iv) add a new GSD Rule 50A and MBSD Rule 40A to address situations in which it is necessary to disconnect a Member, EPN User, third party service provider, or service bureau due to an imminent

threat of harm to FICC, Members, EPN Users and/or other market participants. Each of the proposed changes is described in greater detail below.

(i) FICC Confidentiality Requirements

Section 5 of GSD Rule 2A,⁴ Section 4 of GSD Rule 3,⁵ Section 10 of GSD Rule 3,⁶ Section 2(j) of GSD Rule 3A,⁷ Section 3(e) of GSD Rule 3B,⁸ Section 5(k) of GSD Rule 3B,⁹ Section 6 of MBSD Rule 2A,¹⁰ Section 3 of MBSD Rule 3,¹¹ Section 9 of MBSD Rule 3¹² and Section 9 of EPN Rule 1 of Article III of the EPN Rules¹³ each contain provisions relating to confidentiality of information furnished by participants to FICC (collectively, the “FICC Confidentiality Requirements”). Each of the FICC Confidentiality Requirements provides that either (a) such furnished information will be held by FICC in the same degree of confidence as may be required by law or the rules and

⁴ Section 5 of GSD Rule 2A, *supra* note 3. GSD Rule 2A relates to initial membership requirements including information that FICC may require applicants to furnish to become Members of FICC.

⁵ Section 4 of GSD Rule 3, *supra* note 3. GSD Rule 3 relates to ongoing membership requirements including information that FICC may require Members to furnish to FICC to continue membership at FICC.

⁶ Section 10 of GSD Rule 3, *supra* note 3. Section 10 of GSD Rule 3 states that the books and records of Members, and in the case of a Registered Investment Company Netting Member, their Controlling Management, shall be open to inspection and that FICC shall be furnished certain information.

⁷ Section 2(j) of GSD Rule 3A, *supra* note 3. GSD Rule 3A relates to the rights, liabilities and obligations of Sponsoring Members and Sponsored Members including information that FICC may require Sponsoring Members, Sponsored Members and applicants to become Sponsoring Members or Sponsored Members, to furnish to FICC.

⁸ Section 3(e) of GSD Rule 3B, *supra* note 3. GSD Rule 3B relates to the rights, liabilities and obligations of CCIT Members including information that FICC may require CCIT Members and applicants to become CCIT Members to furnish to FICC.

⁹ Section 5(k) of GSD Rule 3B, *supra* note 3. Section 5(k) of GSD Rule 3B states that the books and records of CCIT Members, and their Controlling Management, shall be open to inspection and that FICC shall be furnished certain information.

¹⁰ Section 6 of MBSD Rule 2A, *supra* note 3. MBSD Rule 2A relates to initial membership requirements including information that FICC may require applicants to furnish to become Clearing Members of FICC.

¹¹ Section 3 of MBSD Rule 3, *supra* note 3. MBSD Rule 3 relates to ongoing membership requirements including information that FICC may require Members to furnish to FICC to continue membership in FICC.

¹² Section 9 of MBSD Rule 3, *supra* note 3. Section 9 of MBSD Rule 3 states that the books and records of Members shall be open to inspection and that FICC shall be furnished certain information.

¹³ Section 9 of EPN Rule 1 of Article III of the EPN Rules, *supra* note 3. Rule 1 of Article III of the EPN Rules relates to initial and ongoing requirements to become and continue to be an EPN User including information that FICC may require applicants or EPN Users to provide to FICC.

regulations of the appropriate regulatory body having jurisdiction over the participant or (b) the rights of FICC to inspect books and records or receive information is subject to any applicable laws or rules or regulations of regulatory bodies having jurisdiction over the participant that relate to confidentiality of records. FICC is proposing to update the FICC Confidentiality Requirements because such provisions (i) may result in unequal treatment of participants due to differing laws or regulations of regulatory bodies, (ii) may result in a potential conflict of laws where rules or regulations governing a regulatory body of a participant differ from the laws applicable to FICC, or a participant has multiple regulatory bodies whose rules conflict, (iii) are burdensome as they require FICC to track the rules and regulations of each regulatory body of its participants, and ensure that information provided by participants to FICC is held in confidence to the same degree as it is held by such regulatory bodies, or to determine what applicable laws or rules or regulations of regulatory bodies that relate to confidentiality of records affect FICC's rights to receive information and (iv) are unnecessary as FICC has sufficient protections in place relating to protection and confidentiality of participant data.

The regulatory bodies that have jurisdiction over participants differ by participant depending on certain criteria of each participant, including the type of entity of the participant, where the participant was organized, the types of businesses in which the participant engages and where the participant is doing business. In addition, many participants are regulated by more than one regulatory body. As a result, a requirement to maintain confidentiality standards for information provided by a participant or the right to receive information based on the regulatory body or bodies that regulate such participant result in varying standards of confidentiality for participants that are regulated by different regulatory bodies. Such varying standards may result in unequal treatment of participants due to differing laws or regulations of the regulatory body or bodies governing such participants. In addition, such varying standards may result in a potential conflict of laws where rules or regulations governing a regulatory body of a participant differ from the laws applicable to FICC or an entity that has multiple regulatory bodies whose rules conflict.

FICC believes that it is unnecessarily burdensome to determine the rules and regulations of each of the regulatory bodies that regulate its participants.

³ Capitalized terms not defined herein are defined in the GSD Rules, MBSD Clearing Rules or the EPN Rules, as applicable, available at <https://www.dtcc.com/legal/rules-and-procedures>.

Such regulatory bodies include numerous U.S. federal and state regulators as well as foreign national, state and local regulators. FICC proposes revising the language in the FICC Confidentiality Requirements to maintain one confidentiality standard for all participants rather than maintaining potentially different confidentiality standards for participants based on the various, unrelated regulatory bodies regulating such participants. FICC is proposing to replace the existing language in the FICC Confidentiality Requirements with language that would provide that FICC will hold non-public information furnished pursuant to those Rules in confidence as may be required under the law or the rules and regulations applicable to FICC that relate to the confidentiality of records. Such laws, rules and regulations would include national, state and foreign laws governing confidentiality of data that are applicable to FICC in connection with its collection and disclosure of data.

FICC believes that the rules and regulations applicable to FICC governing the use and disclosure of confidential information provide standards that are representative of those of the various regulatory bodies governing its participants. As a result, FICC does not believe that the proposed rule change relating to the FICC Confidentiality Requirements would result in any change to FICC's practices relating to data protection and confidentiality of information provided by participants.

(ii) Participant Confidentiality Requirements

Historically, FICC has generally not provided, nor been requested to provide, information that contains confidential or proprietary information of FICC or its affiliates to its participants except for information necessary for participants and their service providers and service bureaus to connect to FICC and to participate in the services that FICC offers to its participants. While certain information is protected by intellectual property rights of FICC and its affiliates under applicable intellectual property laws, such as copyright laws and trademark laws, the Rules do not include any express obligations for participants to protect confidential information received by them from FICC or its affiliates.

In connection with the development of cyber and information security programs pursuant to applicable regulatory requirements by participants, FICC and its parent company, The

Depository Trust & Clearing Corporation ("DTCC"), have received an increasing number of requests from participants for confidential and proprietary information of FICC and DTCC.¹⁴ This includes, for example, information regarding DTCC's network operations and data security practices, legal settlements, and other information. Additionally, in the event there is a cyber incident relating to a participant, FICC or DTCC may be requested to disclose confidential information regarding its cyber threat indicators, sources of cyber threat information, or other information and actions taken related to a cyber event.

In order to provide for contractual protections for such confidential information of DTCC, FICC and DTCC's other subsidiaries, FICC is proposing to add provisions to the Rules that would require participants to maintain confidential information of FICC and its affiliates that FICC provides to such participants in confidence and not to disclose such confidential information except as necessary to perform such participant's obligations under FICC's Rules or as otherwise required by applicable law ("Participant Confidentiality Requirements"). The Participant Confidentiality Requirements would provide that in the event of a breach of the Participant Confidentiality Requirements, FICC or DTCC would be entitled to seek any temporary or permanent injunctive or other equitable relief in addition to any monetary damages under the Rules. In addition, as with any failure to comply with its Rules, FICC would have the ability to impose other disciplinary proceedings or restrictions on access to services as provided in the Rules for failure to comply with the Participant Confidentiality Requirements.

(iii) Market Disruption Events

GSD Rule 50 and MBSD Rule 40 (Market Disruption and Force Majeure)¹⁵ (the "Force Majeure Rule") contain provisions that identify the events or circumstances that would be considered a Market Disruption Event, including, for example, events that lead

to the suspension or limitation of trading or banking in the markets in which FICC operates, or the unavailability or failure of any material payment, bank transfer, wire or securities settlement systems.¹⁶ The Force Majeure Rule set forth in MBSD Rule 40 is also incorporated into the EPN Rules, and EPN Users are treated as Members for purposes of the EPN Rules, and references to "Rules" and "Procedures" are treated as references to EPN Rules for purposes of the EPN Rules.¹⁷ Under the Force Majeure Rule, during the pendency of a Market Disruption Event, FICC would be entitled to (i) suspend the provision of any or all services and (ii) take, or refrain from taking, or require Members to take, or refrain from taking, any actions FICC considers appropriate to address, alleviate, or mitigate the event and facilitate the continuation of FICC's services as may be practicable.¹⁸

Section 2 of the Force Majeure Rule provides that the Board of Directors may determine the existence of a Market Disruption Event and the actions to be taken in response thereto.¹⁹ However, if the Board of Directors is unable to convene, the Force Majeure Rule provides that certain officers may make such determination, on an interim basis, which determination is then ratified, modified or rescinded as soon as practicable by the Board of Directors. The officers that may make such determination are all senior executive officers of FICC: Chief Executive Officer, Chief Financial Officer, Group Chief Risk Officer and General Counsel.

The proposed rule change would add two senior executive officers of FICC, the Chief Information Officer and the Head of Clearing Agency Services, to the list of officers that could make such determination if the Board of Directors is unable to convene. These two officers, like the other senior executive officers currently listed in the Rules, maintain senior executive level positions at FICC, oversee divisions of FICC, and hold positions at FICC that would provide them a necessary global view into FICC's operations and systems to enable them to determine the existence of a Market Disruption Event in the event that the Board of Directors is unable to convene. Adding these two additional officers would facilitate FICC's ability to implement its emergency procedures in the event of a Market Disruption Event.

¹⁴ *Id.*

¹⁵ See Section 5 of EPN Rule 1 of Article III of the EPN Rules, *supra* note 3.

¹⁶ *Id.*

¹⁷ Section 2 of GSD Rule 50 and Section 2 of MBSD Rule 40, *supra* note 3.

¹⁴ DTCC provides a set of core business processes for FICC and DTCC's other subsidiaries, including the technology systems and networks that provide connectivity between FICC and its participants and that provide the ability of FICC to provide the services as required under its Rules. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides relevant services to FICC and DTCC's other subsidiaries.

¹⁵ GSD Rule 50 and MBSD Rule 40, *supra* note 3. The Force Majeure Rule is identical in the GSD Rules and the MBSD Rules.

(iv) Systems Disconnect: Threat of Significant Impact to FICC's Systems

The proposed rule change would add a new GSD Rule 50A and an identical new MBSD Rule 40A (Systems Disconnect: Threat of Significant Impact to the Corporation's Systems) ("Systems Disconnect Rule") that would address situations in which FICC determines it is necessary for FICC to disconnect a single or limited number of Members, or third party service providers or service bureaus used by Members to connect to FICC²⁰ (collectively, "DTCC Systems Participants") from FICC's systems or network due to an imminent threat of harm to FICC's or DTCC's systems. The imminent threat could be the result of a system disruption or cyber incident applicable to the DTCC Systems Participants. This would allow DTCC to work with the affected participants while protecting FICC, its systems and its other participants. Like the Force Majeure Rule set forth in MBSD Rule 40, the new MBSD Rule 40A would be incorporated into the EPN Rules, and EPN Users would be treated as Members, and references to "Rules" and "Procedures" would be treated as references to EPN Rules for purposes of the EPN Rules.

The proposed Systems Disconnect Rule would be structured similarly to the Force Majeure Rule. The Systems Disconnect Rule would address FICC's authority to take certain actions upon the occurrence, and during the pendency, of a Major Event. A "Major Event" would be defined as the happening of one or more "Systems Disruption(s)" (as defined below) that is reasonably likely to have a significant impact on FICC's operations, including the "DTCC Systems" (as defined below), that affect the business, operations, safeguarding of securities or funds, or physical functions of Members and/or other market participants. "Systems Disruption" would be defined as the unavailability, failure, malfunction, overload, or restriction (whether partial or total) of a DTCC Systems Participant's systems that disrupts or degrades the normal operation of such DTCC Systems Participant's systems; or anything that impacts or alters the normal communication or the files that are received, or information transmitted, to or from the DTCC Systems. "DTCC Systems" would be defined as the systems, equipment and technology networks of DTCC, FICC and/or their

Affiliates,²¹ whether owned, leased, or licensed, software, devices, IP addresses or other addresses or accounts used in connection with providing the services set forth in the Rules, or used to transact business or to manage the connection with FICC.

The proposed Systems Disconnect Rule would allow FICC to mitigate the effect of such events by facilitating the continuity of services (or, if deemed necessary, the temporary suspension of services). To that end, under the proposed Systems Disconnect Rule, FICC would be entitled, during the pendency of a Major Event, to (1) disconnect a DTCC Systems Participant's systems from the DTCC Systems, (2) suspend the receipt and/or transmission of files or communications to or from the DTCC Systems Participant to the DTCC Systems and/or (3) take, or refrain from taking, or require a DTCC Systems Participant to take or refrain from taking, any actions that FICC considers appropriate to prevent, address, correct, mitigate or alleviate the Major Event and facilitate the continuation of services as may be practicable and, in that context, issue instructions to the DTCC Systems Participant.

The proposed Systems Disconnect Rule would define the governance procedures for how FICC would determine whether, and how, to implement the provisions of the rule. A determination that a Major Event has occurred could be made by the same officers with delegated authority under the Force Majeure Rule as discussed above (an "Officer Major Event Action"). Following this determination, any management committee on which all of the foregoing officers serve would convene, and FICC would convene a Board of Directors meeting as soon as practicable thereafter, and in any event within five Business Days following such determination, in each case, to ratify, modify, or rescind the Officer Major Event Action. The proposed Systems Disconnect Rule would require Members to notify FICC immediately upon becoming aware of a Major Event, and, likewise, would require FICC to promptly notify the DTCC Systems Participant(s) of any action FICC takes or intends to take with respect to such DTCC Systems Participant(s) pursuant to the proposed rule.

²¹ Affiliate is defined in GSD Rule 1 and MBSD Rule 1, as applicable, and is intended to cover DTCC and DTCC's other subsidiaries that use shared systems with FICC. GSD Rule 1 and MBSD Rule 1, *supra* note 3. See description of the shared systems of DTCC, FICC and DTCC's other subsidiaries, *supra* note 14.

Finally, the Systems Disconnect Rule would address certain miscellaneous matters including: (i) A limitation of liability for any failure or delay in performance, in whole or in part of FICC's obligations under the Rules, arising out of or related to a Major Event, (ii) a statement that the power of FICC to take any action pursuant to the Systems Disconnect Rule also includes the power to repeal, rescind, revoke, amend or vary such action, (iii) a statement that the powers of FICC pursuant to the Systems Disconnect Rule shall be in addition to and not in derogation of, authority granted elsewhere in the Rules to take action as specified therein, (iv) a requirement that Members shall keep any DTCC Confidential Information (as defined below) provided to them by FICC and/or in connection with a Major Event confidential and (v) a statement that in the event of any conflict between the provisions of the Systems Disconnect Rule and any other Rules or Procedures, the provisions of the Systems Disconnect Rule would prevail.

(v) Proposed Rule Changes

The proposed rule change would amend the Rules to make the following changes to implement the changes discussed above:

FICC Confidentiality Requirements Changes

The proposed rule change would amend the FICC Confidentiality Requirements in Section 5 of GSD Rule 2A,²² Section 4 of GSD Rule 3,²³ Section 10 of GSD Rule 3,²⁴ Section 2(j) of GSD Rule 3A,²⁵ Section 3(e) of GSD Rule 3B,²⁶ Section 5(k) of GSD Rule 3B,²⁷ Section 6 of MBSD Rule 2A,²⁸ Section 3 of MBSD Rule 3,²⁹ Section 9 of MBSD Rule 3³⁰ and Section 9 of EPN Rule 1 of Article III of the EPN Rules,³¹ to state as follows:

[A]ny non-public information furnished to the Corporation pursuant to this Rule shall be held in confidence as may be required under the laws, rules and regulations applicable to the Corporation that relate to the confidentiality of records.

As discussed above, the proposed language is intended to provide one

²² Section 5 of GSD Rule 2A, *supra* note 3.

²³ Section 4 of GSD Rule 3, *supra* note 3.

²⁴ Section 10 of GSD Rule 3, *supra* note 3.

²⁵ Section 2(j) of GSD Rule 3A, *supra* note 3.

²⁶ Section 3(e) of GSD Rule 3B, *supra* note 3.

²⁷ Section 5(k) of GSD Rule 3B, *supra* note 3.

²⁸ Section 6 of MBSD Rule 2A, *supra* note 3.

²⁹ Section 3 of MBSD Rule 3, *supra* note 3.

³⁰ Section 9 of MBSD Rule 3, *supra* note 3.

³¹ Section 9 of EPN Rule 1 of Article III of the EPN Rules, *supra* note 3.

²⁰ Some Members use third parties to connect to FICC's systems and/or to send data to FICC and receive data from FICC on the Member's or EPN User's behalf. Such third parties are referred to as "service providers" or "service bureaus" herein.

standard that FICC would apply uniformly to all participants, which assures participants that such information would be held in confidence with appropriate controls. FICC would add “non-public” when describing the information that is subject to the FICC Confidentiality Requirements to make it clear that such requirements would only apply to information that is not public. In addition, in Section 5 of GSD Rule 2A,³² Section 4 of GSD Rule 3,³³ Section 2(j) of GSD Rule 3A,³⁴ and Section 3(e) of GSD Rule 3B,³⁵ FICC would remove the phrase “Except as otherwise provided in Rule 29” or “Except as otherwise provided in Rule 29 (Clearing Data)” because the exception would no longer be needed with the addition of the proposed language. GSD Rule 29³⁶ relates to the ability of FICC to release “Clearing Data” under certain circumstances. Because GSD Rule 29 would be a rule applicable to FICC, it would be covered by the proposed language which states that FICC would hold the information in confidence subject to rules applicable to it. FICC would remove a similar reference to MBSD Rule 22³⁷ in Section 6 of MBSD Rule 2A³⁸ and Section 3 of MBSD Rule 3³⁹ for the same reason. FICC would also amend a sentence in the Board Statements of Policy in the GSD Rules that references the FICC Confidentiality Requirements set forth in GSD Rule 3 to reflect the proposed updated language.

Certain Rules relating to FICC Confidentiality Requirements would also include language relating to Participant Confidentiality Requirements as described below.

Participant Confidentiality Requirements

In order to provide for Participant Confidentiality Requirements, FICC would add provisions in Section 5 of GSD Rule 2A,⁴⁰ Section 4 of GSD Rule 3,⁴¹ Section 2(j) of GSD Rule 3A,⁴² Section 3(e) of GSD Rule 3B,⁴³ Section 6 of MBSD Rule 2A,⁴⁴ Section 3 of MBSD Rule 3,⁴⁵ and Section 9 of EPN

Rule 1 of Article III of the EPN Rules⁴⁶ to state that each participant shall maintain DTCC Confidential Information in confidence to the same extent and using the same means it uses to protect its own confidential information, but no less than a reasonable standard of care, and shall not use DTCC Confidential Information or disclose DTCC Confidential Information to any third party except as necessary to perform its obligations under the Rules or as otherwise required by applicable law. FICC would add a new definition of DTCC Confidential Information in GSD Rule 1 and MBSD Rule 1⁴⁷ to provide that “DTCC Confidential Information” would mean all non-public information provided by DTCC and/or FICC that (i) is marked or otherwise identified in writing prior to disclosure to the recipient as confidential, (ii) is designated by DTCC or FICC as confidential, or (iii) the recipient knows or, under the circumstances surrounding disclosure, ought to reasonably know is confidential. FICC would also add a definition of DTCC in GSD Rule 1 and MBSD Rule 1, and remove a corresponding definition in GSD Rule 22D and MBSD Rule 17B⁴⁸ since it would be defined in GSD Rule 1 and MBSD Rule 1.

FICC would also add a statement in each provision relating to Participant Confidentiality Requirements that each participant acknowledges that a breach of its confidentiality obligations under the Rules may result in serious and irreparable harm to FICC and/or DTCC for which there is no adequate remedy at law. In the event of such a breach by the participant, FICC and/or DTCC would be entitled to seek any temporary or permanent injunctive or other equitable relief in addition to any monetary damages.

Force Majeure Rule Officer Additions

The proposed rule change would add the Chief Information Officer and the Head of Clearing Agency Services to the list of officers that could make a determination of a Market Disruption Event if the Board of Directors is unable to convene in GSD Rule 50 and MBSD Rule 40.⁴⁹

Systems Disconnect Rule

The proposed rule change would add a new GSD Rule 50A and MBSD Rule

40A entitled “Systems Disconnect: Threat of Significant Impact to the Corporation’s Systems” that would address situations in which FICC determines it is necessary for FICC to disconnect a DTCC Systems Participant or DTCC Systems Participants from FICC’s systems or network due to an imminent threat of harm to FICC’s or DTCC’s systems consistent with the description above. The proposed Systems Disconnect Rule would include new definitions for “DTCC Systems,” “DTCC Systems Participant,” “Major Event” and “Systems Disruption” consistent with the descriptions of the Systems Disconnect Rule above.

References to the new GSD Rule 50A would be added to GSD Rule 3A, Section 17(b),⁵⁰ GSD Rule 3B, Section 17(a)⁵¹ and GSD Rule 13, Section 4(m),⁵² in each case, to reflect that the new GSD Rule 50A would apply to Sponsored Members and Sponsoring Members, CCIT Members and Funds-Only Settling Bank Members, respectively, in the same manner as other GSD Rules, including GSD Rule 50. References to the new MBSD Rule 40A would be added to MBSD Rule 3A, Section (m)⁵³ to reflect that the new MBSD Rule 40A would apply to Cash Settling Bank Members in the same manner as other MBSD Rules, including MBSD Rule 40. References to the new MBSD Rule 40A would also be added to Section 5 of EPN Rule 1 of Article III of the EPN Rules⁵⁴ to reflect that the new MBSD Rule 40A would be incorporated into the EPN Rules in the same manner as other MBSD Rules, including MBSD Rule 40.

2. Statutory Basis

FICC believes that the proposal is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered clearing agency. In particular, FICC believes that each of the proposed rule changes is consistent with Section 17A(b)(3)(F) of the Act,⁵⁵ and Rules 17Ad-22(e)(1) and (e)(21)⁵⁶ promulgated under the Act. In addition, FICC believes that the proposed changes to add the two senior executive officers in the Force Majeure Rule and to add the proposed Systems Disconnect Rule

³² Section 5 of GSD Rule 2A, *supra* note 3.

³³ Section 4 of GSD Rule 3, *supra* note 3.

³⁴ Section 2(j) of GSD Rule 3A, *supra* note 3.

³⁵ Section 3(e) of GSD Rule 3B, *supra* note 3.

³⁶ GSD Rule 29, *supra* note 3.

³⁷ MBSD Rule 22, *supra* note 3.

³⁸ Section 6 of MBSD Rule 2A, *supra* note 3.

³⁹ Section 3 of MBSD Rule 3, *supra* note 3.

⁴⁰ Section 5 of GSD Rule 2A, *supra* note 3.

⁴¹ Section 4 of GSD Rule 3, *supra* note 3.

⁴² Section 2(j) of GSD Rule 3A, *supra* note 3.

⁴³ Section 3(e) of GSD Rule 3B, *supra* note 3.

⁴⁴ Section 6 of MBSD Rule 2A, *supra* note 3.

⁴⁵ Section 3 of MBSD Rule 3, *supra* note 3.

⁴⁶ Section 9 of EPN Rule 1 of Article III of the EPN Rules, *supra* note 3.

⁴⁷ GSD Rule 1 and MBSD Rule 1, *supra* note 3.

⁴⁸ GSD Rule 22D and MBSD Rule 17B, *supra* note 3.

⁴⁹ GSD Rule 50 and MBSD Rule 40, *supra* note 3.

⁵⁰ GSD Rule 3A, Section 17(b), *supra* note 3.

⁵¹ GSD Rule 3B, Section 17(a), *supra* note 3.

⁵² GSD Rule 13, Section 4(m), *supra* note 3.

⁵³ MBSD Rule 3A, Section (m), *supra* note 3.

⁵⁴ Section 5 of EPN Rule 1 of Article III of the EPN Rules, *supra* note 3.

⁵⁵ 15 U.S.C. 78q-1(b)(3)(F).

⁵⁶ 17 CFR 240.17Ad-22(e)(1) and (e)(21).

are consistent with Rules 17Ad–22(e)(2) and (e)(17) under the Act.⁵⁷

Section 17A(b)(3)(F)

Section 17A(b)(3)(F) of the Act⁵⁸ requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible and to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.

FICC believes that the proposed changes revising the FICC Confidentiality Requirements and adding the Participant Confidentiality Requirements are each consistent with this provision of the Act. The proposed revisions to the FICC Confidentiality Requirements are consistent with this provision because the proposed revisions would provide a clear and consistent standard relating to how FICC holds the information furnished by participants pursuant to Section 5 of GSD Rule 2A,⁵⁹ Section 4 of GSD Rule 3,⁶⁰ Section 10 of GSD Rule 3,⁶¹ Section 2(j) of GSD Rule 3A,⁶² Section 3(e) of GSD Rule 3B,⁶³ Section 5(k) of GSD Rule 3B,⁶⁴ Section 6 of MBSD Rule 2A,⁶⁵ Section 3 of MBSD Rule 3,⁶⁶ Section 9 of MBSD Rule 3⁶⁷ and Section 9 of EPN Rule 1 of Article III of the EPN Rules.⁶⁸ The confidential information that FICC receives pursuant to these Rules is used by FICC to determine whether to admit a participant as a Member or EPN User, to continue to allow such participant to be a Member or EPN User, or to better understand the risks relating to each participant. Providing a clear and consistent standard would facilitate this process by allowing participants to better understand FICC's obligations with respect to such information and providing a uniform obligation for FICC with respect to such information. FICC believes that facilitating the ability of FICC to evaluate participants would promote the prompt and accurate clearance and settlement of securities

transactions by FICC. As such, FICC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act.⁶⁹

FICC also believes that the proposed rule change adding the Participant Confidentiality Requirements is consistent with this provision of the Act because the proposed revisions to the Participant Confidentiality Requirements would provide a clear and consistent contractual obligation for participants who are requesting confidential information from FICC. Having clear and consistent Rules would help participants to better understand their rights and obligations regarding FICC's clearance and settlement services. The information requested by participants that would be subject to the Participant Confidentiality Requirements would be used by participants to determine whether to participate in FICC's services, FICC system requirements and FICC system safeguards. FICC believes that when Members and EPN Users better understand their rights and obligations regarding FICC's clearance and settlement services, they can better act in accordance with the Rules. FICC believes that better enabling Members and EPN Users to comply with the Rules would promote the prompt and accurate clearance and settlement of securities transactions by FICC. As such, FICC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act.⁷⁰

FICC believes that the proposed changes to add the two officers to make a determination of a Market Disruption Event and to add the Systems Disconnect Rule in the GSD Rules and the MBSD Rules are also consistent with this provision of the Act because those changes would enhance and streamline FICC's ability to take necessary actions in the event of a Market Disruption Event or a Major Event. Improving the ability of FICC to react to a Market Disruption Event or a Major Event would allow FICC to protect its participants and their ability to promptly and accurately clear and settle securities transactions, and allow FICC to safeguard securities and funds that are in its custody or control. In particular, allowing two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to FICC while maintaining proper risk controls and improve the ability of FICC

to act in the event of a Market Disruption Event. Also, providing for the ability of FICC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect FICC and its participants would, in each case, provide additional tools for FICC in the event of a Major Event.

Improving the governance around the determination of a Market Disruption Event, and the implementation of procedures allowing FICC to disconnect a DTCC Systems Participant or DTCC Systems Participants from FICC's systems or network due to an imminent threat of harm, would improve FICC's ability to address and minimize losses to FICC and its participants. Risks, threats and potential vulnerabilities due to a Market Disruption Event or a Major Event could impact FICC's ability to clear and settle securities transactions, or to safeguard the securities and funds which are in its custody or control, or for which it is responsible. In addition, providing governance around the ability to disconnect a DTCC Systems Participant that is having a systems disruption that could disrupt the ability of FICC or other DTCC Systems Participants from using FICC's systems would remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. Although disconnecting or limiting the service of a DTCC Systems Participant in the event of a Major Event would likely be an impediment to such DTCC Systems Participant, improving FICC's ability to address and minimize losses to FICC and its participants, and reducing risks, threats and potential vulnerabilities due to a Major Event that could impact FICC's ability to clear and settle securities transactions, or to safeguard the securities and funds which are in its custody or control or for which it is responsible, would be consistent with Section 17A(b)(3)(F) of the Act.⁷¹

Therefore, by implementing tools that would help to mitigate these risks, FICC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, assure the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible, and remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and

⁵⁷ 17 CFR 240.17Ad–22(e)(2) and (e)(17).

⁵⁸ 15 U.S.C. 78q–1(b)(3)(F).

⁵⁹ Section 5 of GSD Rule 2A, *supra* note 3.

⁶⁰ Section 4 of GSD Rule 3, *supra* note 3.

⁶¹ Section 10 of GSD Rule 3, *supra* note 3.

⁶² Section 2(j) of GSD Rule 3A, *supra* note 3.

⁶³ Section 3(e) of GSD Rule 3B, *supra* note 3.

⁶⁴ Section 5(k) of GSD Rule 3B, *supra* note 3.

⁶⁵ Section 6 of MBSD Rule 2A, *supra* note 3.

⁶⁶ Section 3 of MBSD Rule 3, *supra* note 3.

⁶⁷ Section 9 of MBSD Rule 3, *supra* note 3.

⁶⁸ Section 9 of EPN Rule 1 of Article III of the EPN Rules, *supra* note 3.

⁶⁹ 15 U.S.C. 78q–1(b)(3)(F).

⁷⁰ *Id.*

⁷¹ *Id.*

settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.⁷²

Rule 17Ad-22(e)(1)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(1) promulgated under the Act,⁷³ which requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities in all relevant jurisdictions.

Establishing clear and consistent rules for each participant with respect to the FICC Confidentiality Requirements would allow FICC to maintain one confidentiality standard for all participants rather than maintaining potentially different confidentiality standards for participants based on the various, unrelated regulatory bodies governing such participants. In addition, setting forth a clear contractual obligation relating to Participant Confidentiality Requirements would enhance the understanding of the participants receiving information from FICC and allow FICC to treat participants equally with respect to how the information furnished to participants should be protected by the participants.

Adding the two officers to make a determination of a Market Disruption Event and adding the Systems Disconnect Rule are also consistent with Rule 17Ad-22(e)(1) under the Act because those changes would describe the circumstances under which FICC could take actions in the event of a Market Disruption Event or a Major Event that are necessary to protect FICC and its participants. Providing clear guidelines with respect to Market Disruption Events and Major Events would allow participants to understand the rights and obligations of the participants in the event of a Market Disruption Event or a Major Event.

Therefore, by establishing uniform and clear standards with respect to its receipt and furnishing of confidential information, and by providing clear rights and obligations of FICC and its participants with respect to Market Disruption Events and Major Events, FICC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(1) promulgated under the Act.⁷⁴

Rule 17Ad-22(e)(21)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(21) promulgated under the Act,⁷⁵ which requires FICC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves. The proposed rule change would streamline the FICC Confidentiality Requirements by providing that FICC would apply one standard for all participants relating to confidential information sent to FICC by participants, which would enhance (i) efficiency by avoiding applying varying standards of confidentiality based on the rules and regulations of the varying regulatory bodies that regulate the participants, and (ii) effectiveness by reducing potential conflicts of laws and providing equal treatment to participants relating to such confidential information.

The addition of the Participant Confidentiality Requirements would also provide a uniform and easily discernable requirement for all participants with respect to confidential information provided by FICC allowing FICC to provide necessary information to such participants in a safe and efficient manner. Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to FICC while maintaining proper risk controls and improve the ability of FICC to act quickly, efficiently and effectively in a Market Disruption Event to address and minimize losses. Also, providing for the ability of FICC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect FICC and its participants would, in each case, provide additional tools for FICC in the event of a Major Event and improve FICC's ability to act quickly, efficiently and effectively in the event of a Major Event to address and minimize losses.

Therefore, by establishing a more efficient and effective process for the treatment of confidential language, and establishing procedures designed to improve FICC's ability to act quickly, efficiently and effectively in the event of a Market Disruption Event and a Major

Event, FICC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(21) promulgated under the Act.⁷⁶

Rule 17Ad-22(e)(2)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(2) promulgated under the Act,⁷⁷ which requires FICC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and that specify clear and direct lines of responsibility.

Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to FICC while maintaining proper risk controls, and improve the ability of FICC to act quickly, efficiently and effectively in a Market Disruption Event and mitigate any impact from such Market Disruption Event. Adding these officers to the governance procedures relating to a determination of a Market Disruption Event would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Market Disruption Event, consistent with Rule 17Ad-22(e)(2) under the Act.⁷⁸

Adding the governance procedures relating to making a determination of a Major Event in the Systems Disconnect Rule is also consistent with Rule 17Ad-22(e)(2) promulgated under the Act.⁷⁹ Identifying the officers that have the ability to determine if there is a Major Event, and providing for the ability of any management committee on which all of such officers serve and the Board of Directors to ratify, modify or rescind any determination of a Major Event by an officer would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Major Event, consistent with Rule 17Ad-22(e)(2).⁸⁰

Rule 17Ad-22(e)(17)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(17)(i) promulgated under the Act,⁸¹ which requires FICC to establish, implement, maintain and

⁷² *Id.*

⁷³ 17 CFR 240.17Ad-22(e)(1).

⁷⁴ *Id.*

⁷⁵ 17 CFR 240.17Ad-22(e)(21).

⁷⁶ *Id.*

⁷⁷ 17 CFR 240.17Ad-22(e)(2).

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ 17 CFR 240.17Ad-22(e)(17)(i).

enforce written policies and procedures reasonably designed to manage the covered clearing agency's operational risks by identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls.

Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to FICC while maintaining proper risk controls and improve the ability of FICC to act quickly, efficiently and effectively in a Market Disruption Event and mitigate any impact from such Market Disruption Event. Also, providing for the ability of FICC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect FICC and its participants would, in each case, provide additional tools for FICC in the event of a Major Event and improve FICC's ability to act quickly, efficiently and effectively in the event of a Major Event and mitigate any impact from such Major Event.

Therefore, by providing clear, efficient procedures of FICC and its participants with respect to Market Disruption Events and Major Events that help identify and mitigate operational risks, FICC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(17)(i) promulgated under the Act.⁸²

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe that the proposed changes relating to the FICC Confidentiality Requirements would have any impact on competition. These changes would provide one standard for how FICC treats participant information furnished subject to the FICC Confidentiality Requirements but would not affect the information that the participants are required to provide or affect the manner in which the participants must provide the information. As such, FICC believes these proposed rule changes would not have any impact on competition.

FICC does not believe the proposed changes relating to adding Participant Confidentiality Requirements would have any impact on competition. Although the addition of the Participant

Confidentiality Requirements would be adding obligations on participants with respect to how they treat confidential or proprietary information of FICC or its affiliates, such obligations would be minimal because FICC would only require that such participants hold such confidential information using the same means they use to protect their own confidential information but not less than a reasonable standard of care. The use of this standard would protect FICC by providing a clear legal obligation to protect such information but would not be burdensome or expensive for participants, and therefore FICC believes that it would not have any impact on competition.

FICC does not believe the changes relating to adding the two officers to make a determination of a Market Disruption Event would have any impact on competition. The proposed rule change would add two senior executive officers of FICC, the Chief Information Officer and the Head of Clearing Agency Services, to the list of officers that could make a determination of a Market Disruption Event if the Board of Directors is unable to convene. Such addition would provide additional officers who could determine whether there is a Market Disruption Event but would not otherwise affect the rights of participants or FICC in the determination of a Market Disruption Event or if a Market Disruption Event is declared. Therefore, FICC does not believe that the addition of the two officers would have any impact on competition.

FICC does not believe that the changes relating to adding the Systems Disconnect Rule would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act.⁸³ To the extent that FICC determines that there is a Major Event, it could take or refrain from taking actions, or require participants to take or refrain from taking actions, that could burden competition because such requirements could cause participants to incur additional costs, allow FICC to suspend services or communications or disconnect a DTCC Systems Participant from the DTCC Systems. FICC believes such burden on competition could be significant but would be both necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act,⁸⁴ for the reasons described below.

FICC believes that the proposed changes to add the Systems Disconnect

Rule are necessary in furtherance of the purposes of Section 17A(b)(3)(F) of the Act,⁸⁵ and Rules 17Ad-22(e)(1), (e)(2), (e)(17) and (e)(21) promulgated under the Act.⁸⁶ The proposed changes to add the Systems Disconnect Rule would (i) improve the ability of FICC to react to a Major Event allowing FICC to protect itself and its participants and their ability to promptly and accurately clear and settle securities transactions, and allow FICC to safeguard securities and funds that are in its custody or control, consistent with the requirements of Section 17A(b)(3)(F) of the Act,⁸⁷ (ii) provide clear guidelines with respect to Major Events that would allow participants to understand the rights and obligations of the participants and FICC in the event of a Major Event, consistent with Rule 17Ad-22(e)(1) promulgated under the Act,⁸⁸ (iii) identify the officers that have the ability to determine if there is a Major Event, and provide for the ability of any management committee on which all of such officers serve, and the Board of Directors, to ratify, modify or rescind any determination of a Major Event by an officer, which would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Major Event, consistent with Rule 17Ad-22(e)(2) promulgated under the Act,⁸⁹ (iv) improve the ability of FICC to act quickly, efficiently and effectively in the event of a Major Event, and mitigate any impact from such event by providing clear, efficient procedures of FICC and its participants with respect to such event consistent with the requirements of Rule 17Ad-22(e)(17)(i) promulgated under the Act⁹⁰ and (v) establish procedures designed to improve FICC's ability to act quickly, efficiently and effectively in the event of a Major Event, consistent with the requirements of Rule 17Ad-22(e)(21) promulgated under the Act.⁹¹

In addition, FICC believes that the proposed changes to add the Systems Disconnect Rule are appropriate in furtherance of the Act. Such changes have been designed to improve the ability of FICC to act quickly, efficiently and effectively in the event of a Major Event, and mitigate any impact from such event while also providing the

⁸⁵ 15 U.S.C. 78q-1(b)(3)(F).

⁸⁶ 17 CFR 240.17Ad-22(e)(1), (e)(2), (e)(17) and (e)(21).

⁸⁷ 15 U.S.C. 78q-1(b)(3)(F).

⁸⁸ 17 CFR 240.17Ad-22(e)(1).

⁸⁹ 17 CFR 240.17Ad-22(e)(2).

⁹⁰ 17 CFR 240.17Ad-22(e)(17)(i).

⁹¹ 17 CFR 240.17Ad-22(e)(21).

⁸² *Id.*

⁸³ 15 U.S.C. 78q-1(b)(3)(I).

⁸⁴ *Id.*

participants clear guidelines with respect to such event to allow participants to understand their rights and obligations. Such changes have also been designed to apply uniformly to all Members and EPN Users in the event of a Major Event and should not affect FICC's day-to-day operations under normal circumstances, or in the management of a typical Member or EPN User default scenario or non-default event.

Therefore, FICC does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.⁹²

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-FICC-2021-004 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-FICC-2021-004. 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 FICC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-FICC-2021-004 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹³

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-14796 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92345; File No. SR-NASDAQ-2021-055]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Listing Rule 5910 To Establish Entry and All-Inclusive Annual Listing Fees for Companies Listing Under IM-5101-2 on the Nasdaq Global Market

July 7, 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 June 28, 2021, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Listing Rule 5910 to establish Entry and All-Inclusive Annual Listing Fees for companies listing under IM-5101-2 (companies whose business plan is to complete one or more acquisitions) on the Nasdaq Global Market.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁹² 15 U.S.C. 78q-1(b)(3)(I).

⁹³ 17 CFR 200.30-3(a)(12).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Historically, companies whose business plan is to complete an initial public offering and engage in a merger or acquisition with one or more unidentified companies within a specific period of time, as described in IM-5101-2, ("Acquisition Companies") would choose to list on the Nasdaq Capital Market instead of the Nasdaq Global Market, primarily because it has lower fees. However, nothing in Nasdaq's rules prohibits an Acquisition Company from listing on the Global Market.³ More recently, certain Acquisition Companies have sought to list on the Nasdaq Global Market. In particular, Nasdaq notes that a recent SEC statement about accounting treatment by Acquisition Companies⁴ has resulted in some Acquisition Companies adopting different accounting practices and, as a result, having insufficient equity to qualify for initial listing on the Nasdaq Capital Market. However, these companies could list on the Nasdaq Global Market or on competing marketplaces, which permit listing without any minimum equity requirement.⁵ Nasdaq wishes to revise the fees for Acquisition Companies listing on the Nasdaq Global Market so that its fees for these companies seeking to list on that market tier will be competitive with other markets where they can list.

As described below, Nasdaq believes that this fee change is appropriate because Acquisition Companies listed on the Nasdaq Global Market ("Global Market Acquisition Companies") receive the same services as Acquisition Companies listed on the Nasdaq Capital Market ("Capital Market Acquisition Companies"). For example, Global Market Acquisition Companies are not eligible to receive services from Nasdaq

under IM-5900-7, unlike other companies listing on the Nasdaq Global Market but like Capital Market Acquisition Companies. Moreover, Global Market Acquisition Companies require fewer regulatory resources than other companies listing on the Nasdaq Global Market and the same regulatory resources as Capital Market Acquisition Companies. Therefore, Nasdaq proposes to adopt Entry and All-Inclusive Annual Listing Fees for Global Market Acquisition Companies that are identical to the fees currently charged Capital Market Acquisition Companies.

As proposed, Nasdaq would amend Rule 5910(a)(1) to include the following entry fee schedule applicable to Global Market Acquisition Companies, based on the number of shares outstanding: Up to 15 million shares outstanding, \$50,000; over 15 million shares outstanding, \$75,000. These are the same fees charged Capital Market Acquisition Companies under Rule 5920(a)(1).⁶

In addition, Nasdaq would amend Rule 5910(b)(2) to include the following All-Inclusive Annual Fee schedule applicable to Global Market Acquisition Companies, based on the number of shares outstanding: Up to 10 million shares outstanding, \$44,000; between 10,000,001 and 50 million shares outstanding, \$58,000; over 50 million shares outstanding, \$79,000. These are the same fees charged Capital Market Acquisition Companies under Rule 5920(b)(2)(A).

The proposed Entry Fee and All-Inclusive Annual Fee would be lower than the fees applicable to other companies listing on the Nasdaq Global Market. However, Nasdaq notes that Acquisition Companies differ in some important respects from traditional operating companies and believes that these differences make it reasonable to adopt separate fee schedules for Acquisition Companies.

An Acquisition Company, when it first lists under IM-5101-2, will only be listed for a brief period of time while looking to complete a business combination. Under IM-5101-2, an Acquisition Company must complete a business combination within three years, although the governing documents of many Acquisition Companies require the business combination occur in a shorter time. If the Acquisition Company does not complete a business combination it must return the funds held in trust to

the company's shareholders and dissolve the company. Accordingly, Acquisition Companies must assess the economic value of a listing on the basis of a potentially very brief period of listing. Given the much shorter average length of an Acquisition Company's listing, Nasdaq believes it is reasonable to charge Acquisition Companies listed on the Nasdaq Global Market lower Entry Fees than operating companies.

Further, upon first listing, Acquisition Companies are not eligible to receive services from Nasdaq under IM-5900-7, unlike other companies listing on the Nasdaq Global Market, and therefore Nasdaq believes that it is reasonable to charge Acquisition Companies that list on the Nasdaq Global Market lower Entry Fees than operating companies.⁷ While Acquisition Companies are searching for a target to complete a business combination Nasdaq has observed that their shares typically trade less frequently than comparable operating companies.⁸ Accordingly, they are less reliant on the Exchange's trading platform and need less support from the Nasdaq Market Intelligence Desk and require fewer regulatory resources to monitor trading. In addition, in Nasdaq's experience their periodic filings tend to be simpler than those of operating companies, they issue fewer press releases prior to announcing their business combination, and their prices generally remain stable resulting in very few deficiencies related to their price or market value measures, all of which also leads to their requiring fewer regulatory resources.⁹ Accordingly, Nasdaq believes that it is reasonable to charge Acquisition Companies listed on the Nasdaq Global Market lower All-Inclusive Annual Fees than operating companies.

Nasdaq does not expect the financial impact of this proposal to be material in terms of the level of listing fees collected from issuers. Specifically, Nasdaq notes that without the proposed fee changes, many of the Acquisition Companies that do not qualify for the Nasdaq Capital Market would list on a market with lower listing fees instead of

³ Nasdaq Listing Rule 5310(i) provides that an Acquisition Company is not eligible to list on the Nasdaq Global Select Market.

⁴ *Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (SPACs)*, by John Coates, Acting Director of the Division of Corporation Finance, and Paul Munter, Acting Chief Accountant (April 12, 2021), available at: <https://www.sec.gov/news/public-statement/accounting-reporting-warrants-issued-spacs>.

⁵ Nasdaq Rule 5405(b)(3) allows a company to list on the Nasdaq Global Market with no equity if it has a Market Value of Listed Securities of \$75 million and a Market Value of Unrestricted Publicly Held Shares of \$20 million, along with satisfying price, publicly held shares, round lot holder and market maker requirements. See also Section 102.06 of the NYSE Listed Company Manual.

⁶ Nasdaq would also add sub-paragraph numbering to Rule 5910(a)(1) to improve readability and move language about the deferral of the Entry Fee applicable to Acquisition Companies to new Rule 5910(a)(1)(B).

⁷ An Acquisition Company is offered certain services under IM-5900-8 following the public announcement that the company entered into a binding agreement for the business combination, however these services are available to Acquisition Companies listed on either the Nasdaq Global Market or the Nasdaq Capital Market.

⁸ This trading pattern will generally change once the Acquisition Company announces its business combination target.

⁹ While Nasdaq has experienced few deficiencies recently, historically some Acquisition Companies became non-compliant with the holder requirement. See, e.g., Nasdaq Rule 5550(a)(3) (requiring at least 300 Public Holders for continued listing on the Nasdaq Capital Market).

on Nasdaq, in which case Nasdaq would not collect any fees. Moreover, once an Acquisition Company completes a business combination it would be subject to the higher fee schedule applicable to operating companies.¹⁰ Accordingly, the Exchange believes that the proposed rule change will not impact the Exchange's resource commitment to its regulatory oversight of the listing process or its regulatory programs.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹¹ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹² in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As a preliminary matter, Nasdaq competes for listings with other national securities exchanges and companies can easily choose to list on, or transfer to, those alternative venues. As a result, the fees Nasdaq can charge listed companies are constrained by the fees charged by its competitors and Nasdaq cannot charge prices in a manner that would be unreasonable, inequitable, or unfairly discriminatory.

The proposed fees are being implemented to avoid charging a higher fee to an Acquisition Company that is unable to list on the Nasdaq Capital Market but is able to list on the Nasdaq Global Market due to insufficient shareholders' equity and to enable Nasdaq to compete with other markets that can list such Acquisition Companies. Nasdaq believes it is equitable under Section 6(b)(4) of the Act¹³ to charge Global Market Acquisition Companies the same fees as Capital Market Acquisition Companies given that they are treated the same regardless of whether they are listed on the Global or Capital Market. For example, as described below, neither is eligible to receive services upon first listing, each receive identical services from Nasdaq upon announcing a

business combination and each uses similar regulatory resources.

Moreover, the Exchange believes that the proposal is not unfairly discriminatory, because Acquisition Companies are shell companies with no business operations, and, while searching for a target, their shares trade less frequently on the Exchange than operating companies. In Nasdaq's experience, Acquisition Companies are less reliant on the Exchange's trading platform and need less support from the Nasdaq Market Intelligence Desk and require fewer regulatory resources to monitor trading. In addition, in Nasdaq's experience, their periodic filings tend to be simpler than those of operating companies, they issue fewer press releases prior to announcing their business combination, and their prices generally remain stable resulting in very few deficiencies related to their price or market value measures, all of which also leads to their requiring fewer regulatory resources. Further, Acquisition Companies are not eligible to receive services from Nasdaq under IM-5900-7, unlike other companies listing on the Nasdaq Global Market. While an Acquisition Company is offered certain services under IM-5900-8 following the public announcement that the company entered into a binding agreement for the business combination, these services are available to Acquisition Companies listed on either the Nasdaq Global Market or the Nasdaq Capital Market. Therefore, Nasdaq believes that it is appropriate, and not unfairly discriminatory, to charge lower fees to Global Market Acquisition Companies than are charged to operating companies listed on the Nasdaq Global Market.

Finally, Nasdaq competes for listings with the New York Stock Exchange, which has adopted lower fees for Acquisition Companies than for operating companies¹⁴ and can list certain Acquisition Companies that have insufficient shareholders' equity to list on the Nasdaq Capital Market, but can list on the Nasdaq Global Market. Nasdaq believes that this competition is a non-discriminatory reason to reduce the fees for Acquisition Companies seeking to list on the Nasdaq Global Market.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

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.

The proposed new fee schedule will be available to all similarly situated issuers on the same basis. The Exchange does not believe that the proposed fees will have any meaningful effect on the competition among issuers listed on the Exchange.

The Exchange operates in a highly competitive market in which issuers can readily choose to list new securities on other exchanges and transfer listings to other exchanges if they deem fee levels at those other venues to be more favorable. Because competitors are free to modify their own fees in response, and because issuers may change their listing venue, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition. Nasdaq notes that the New York Stock Exchange is its primary competitor for listing Acquisition Companies and that market has already adopted a lower fee for Acquisition Companies than for operating companies.¹⁵

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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)(ii) of the Act.¹⁶

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

¹⁰ Nasdaq notes that its All-Inclusive Annual Fee is assessed on January 1 of each year and neither the Acquisition Company nor the post-business combination entity would pay any additional fees in the year of the business combination (irrespective of the form or structure of that combination). However, the post-business combination would begin paying the higher Annual Fee as of January 1 of the following year.

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(4) and (5).

¹³ 15 U.S.C. 78f(b)(4).

¹⁴ See Section 902.11 of the NYSE Listed Company Manual, imposing a flat \$85,000 Listing Fee for an Acquisition Company and providing a limit of \$85,000 on annual fees payable by an Acquisition Company. Under NYSE Listing Rules, a SPAC can list without regard to the amount of its stockholders' equity.

¹⁵ *Id.*

¹⁶ 15 U.S.C. 78s(b)(3)(A)(ii).

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2021-055 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-NASDAQ-2021-055. 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-NASDAQ-2021-055 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-14800 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92339; File No. SR-DTC-2021-010]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Reorganizations Service Guide

July 7, 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 July 1, 2021, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(4) thereunder.⁴ 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 proposed rule change consists of changes to the Reorganizations Service Guide (the "Guide"),⁵ as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The purpose of the proposed rule change is to amend the Guide to provide

Participants with the option to submit instructions via Application Program Interface ("API") and ISO 20022 real-time messaging (collectively, "Automated Instruction Messaging") for Automated Tender Offer Program ("ATOP")⁶-eligible voluntary reorganizations offers (each, an "ATOP Offer").⁷ DTC is also proposing to amend the Guide to adjust and clarify DTC processing cut-off times for the submission of ATOP Offer instructions ("DTC Cut-Off Time"), and to make technical and ministerial changes to the Guide, as discussed more fully below.

(i) Automated Instruction Messaging

A. Background

When an issuer or agent announces an ATOP Offer, it communicates the details of the offer to DTC, which announces the ATOP Offer to its Participants in accordance with the Guide and applicable Rules. Participants then relay the information to their clients, which, in turn, relay the information to their clients, and so forth, down to the investor level. For example, the ATOP Offer information flows from the issuer/agent to DTC, DTC to Participant, Participant to Investor Manager client, Investment Manager to its investor clients. Each level of the chain solicits and compiles instructions from its clients and submits the instructions back up the chain, until the instructions reach the Participant level. Each Participant compiles and aggregates all instructions received from its clients and submits the instructions to DTC through the PTS PTOF or PBS Voluntary Tenders and Exchanges functions via nonautomated key entry.⁸ The whole process needs to be completed before the DTC Cut-Off Time for the ATOP Offer.

There are certain potential risks and costs associated with manual processing, particularly in connection with voluntary reorganizations

⁶ ATOP is a DTC program through which Participant instructions are transmitted to the agent for an ATOP offers and through which a participant can tender its securities to the agent's account at DTC.

⁷ DTC anticipates implementing Automated Instruction Messaging for Automated Subscription Offer Program ("ASOP")-eligible offers by Q1 2022.

⁸ PTS (Participant Terminal System) and PBS (Participant Browser System) are user interfaces for DTC settlement and asset services functions. PTS is mainframe-based, and PBS is web-based with a mainframe back-end. Participants may use either PTS or PBS, as they are functionally equivalent. PTOF and Voluntary Tenders and Exchanges are functions of PTS and PBS, respectively, that are currently used by Participants to submit instructions, submit protects, submit cover of protects, submit cover of protects on behalf of another Participant, and submit withdrawals on various voluntary reorganization events.

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).

⁵ Each term not otherwise defined herein has its respective meaning as set forth in the Rules, By-Laws and Organization Certificate of DTC (the "Rules") and the Guide, available at <http://www.dtcc.com/legal/rules-and-procedures.aspx>.

¹⁷ 17 CFR 200.30-3(a)(12).

instructions. Nonautomated input may increase the likelihood of errors, which can result in rejected instructions or erroneous elections. Rejected instructions and erroneous elections can delay the submission of the instructions for the ATOP Offer, which typically have to be submitted within a short timeframe. Further, because information about the ATOP Offer and the compilation and transmission of instructions flows across different market segments, the lack of automation and standardization can also lead to errors along the chain. Finally, ATOP Offers are becoming increasingly complex, thereby requiring a greater volume of individual nonautomated input by Participants, which adds to the potential risk of errors and increases the overhead cost for additional personnel and processes to handle the volume.

Therefore, DTC is proposing to provide Participants with the ability to use Automated Instruction Messaging via ISO 20022 messages and API functionality for ATOP-eligible offers. The functionality for the submission of instructions through standardized ISO 20022 messaging already exists at DTC. For example, Participants have the ability to submit ISO 20022 instructions for eligible distributions events.⁹ ISO 20022 is a standard that provides the financial industry with a common language to capture business transactions and associated message flows. The benefits offered by ISO 20022 include, but are not limited to: (i) Greater straight through processing by utilizing a data model that conforms to market practice, and (ii) improved accuracy and less processing risk due to enhanced data elements.

DTC already offers API functionality for the submission of certain instructions to DTC. For example, Participants can currently engage with the DTC ClaimConnect service via APIs.¹⁰ APIs enable the flow of information between computer applications and provide Participants the ability to easily access and evaluate customer data as well as provide Participants with callable endpoints for deleting data resources and for reading and updating data resource values. Stated another way, APIs provides enhanced flexibility for Participants, making the process of accessing from,

and transmitting information to, DTC and its downstream customers more efficient. The flexibility of APIs and its use of modern programming languages provide benefits that include, but are not limited to: (i) Less frequent maintenance, (ii) client development and implementation can be quicker to market, and (iii) more efficient integration channels.

B. Automated Instruction Messaging

Pursuant to the proposed rule change, Automated Instruction Messaging would be available for the following ATOP actions: (i) Accepting an ATOP-Eligible Offer, (ii) Accepting an ATOP-Eligible Offer via Notice of Guaranteed Delivery, (iii) Submitting a Cover of Protect, and (iv) Puts. However, withdrawal or cancellation instructions in connection with the above would still need to be performed via PTS/PBS. In addition, Automated Instruction Messaging for the Submitting a Cover of Protect on Behalf of a Third Party action would not be available.¹¹

Automated Instruction Messaging would consist of (i) Automated Instruction Messages for the input of instructions, and (ii) Automated Response Messages for feedback and status output with respect to submitted instructions. The ISO 20022 Corporate Action Instruction (CAIN) message and the API POST function are Automated Instruction Messages. The ISO 20022 Corporate Action Instruction Status Advice (CAIS) message and the API GET function are Automated Response Messages.

As noted above, automating instructions for ATOP Offers would streamline the flow of information, reducing the costs, errors and risks that are associated with nonautomated processing. Accordingly, pursuant to the proposed rule change, DTC would provide Participants with the ability to automate and standardize the submission of instructions for ATOP Offers through Automated Instruction Messaging.

(ii) Clarification and Adjustment of Certain Cut-off Times for ATOP Offer Instructions

The terms of an ATOP Offer include, among other things, the dates and times by which certain instructions (e.g., acceptances, protects) must be submitted, as well the date and time that the ATOP Offer expires. For ATOP Offers processed through DTC, DTC

establishes a DTC Cut-Off Time, which is the deadline for Participants to submit ATOP Offer instructions to DTC for processing.¹²

DTC is proposing to (i) amend outdated language about the DTC Cut-Off Time for an ATOP Offer with an actual expiration time that is 6:00 p.m. ET or later on the expiration date, and (ii) remove the reference to a 1:00 p.m. ET DTC Cut-Off Time, which, pursuant to the proposed rule change, would no longer be the established DTC Cut-Off Time for an ATOP Offer with an actual expiration time before 5:00 p.m. ET.

The current language in the Guide provides that, unless otherwise specified in the ATOP Offer announcement (i) ATOP Offers being processed by the agent through ATOP (referred to as an "ATOP I" offer, which have an actual expiration time of 5:00 p.m. ET or later) have a DTC Cut-Off Time of 5:00 p.m. ET, and (ii) ATOP Offers being processed by the agent without an electronic connection to ATOP (referred to as an "ATOP II" offer, which typically expires before 5:00 p.m. ET) have a DTC Cut-Off Time of 1:00 p.m.

Pursuant to the proposed rule change, DTC would update the language in the Guide to reflect that for ATOP Offers with an actual expiration time between 6:00 p.m. ET and midnight on expiration date, the DTC Cut-Off Time typically will be 6:00 p.m. ET, instead of 5:00 p.m. ET.¹³ DTC extended this processing window by an additional hour to provide Participants additional time to submit instructions to be processed by DTC and to avoid Participants submitting instructions directly to the agent outside of DTC.

DTC is further proposing to amend the Guide to provide that, with respect to an ATOP Offer with an actual expiration time earlier than 5:00 p.m. ET on expiration date,¹⁴ the DTC Cut-Off Time would vary depending on the particular facts and circumstances of the ATOP Offer and would be announced in the notice of the ATOP Offer.¹⁵

¹² Participants are able to submit ATOP Offer instructions after the DTC Cut-Off Time directly to the agent until the actual expiration time, if provided for under the terms of the ATOP Offer.

¹³ See Important Notice B#11772-19 (July 15, 2019), available at <https://www.dtcc.com/~media/Files/pdf/2019/7/15/11772-19.pdf>.

¹⁴ Although infrequent, there are some circumstances where an ATOP Offer may have an actual expiration time earlier than 5:00 p.m. ET. For example, the expiration time of an ATOP Offer from a jurisdiction in a later time zone could translate in an atypical early expiration time in the eastern time zone.

¹⁵ Pursuant to the proposed rule change, DTC would also remove the references to ATOP I and ATOP II, which are no longer relevant to DTC Cut-

Continued

⁹ Participants can submit ISO 20022 instructions on applicable tax relief, foreign currency payments, dividend reinvestment including opt out and optional dividend events. See DTC Distributions Service Guide, p. 16, available at <http://www.dtcc.com/legal/rules-and-procedures.aspx>.

¹⁰ See ClaimConnect Service Guide, p.8, available at <http://www.dtcc.com/legal/rules-and-procedures.aspx>.

¹¹ DTC anticipates implementing Automated Instruction Messaging for withdrawal and cancellation instructions, as well as for Cover Protect on Behalf of a Third-Party action, by Q1 2022.

DTC is also proposing to amend the Guide to remind Participants that expiration and cutoff times may vary per the terms of the offer and that Participants are independently responsible for confirming both the actual offer expiration date and time and the DTC Cut-off Time and date.

(iii) Proposed Rule Changes

Pursuant to the proposed rule change, DTC is proposing to:

1. Add references to “Automated Instruction Messaging” or “Automated Instruction Message,” as context requires, where other types of instruction input for ATOP-eligible offers (e.g., PTS PTOPTOP and PBS Voluntary Tenders and Exchanges) are referenced.

2. Add references to “Automated Response Message” where other types of response and/or status reports relating to instructions on ATOP-eligible offers (e.g., PTS/PBS, CA Web or Participant Daily Activity Statement) are referenced.

3. In the “Overview” subsection of the “About Reorganization Services”/“Introduction” section, insert (i) references to ISO 20022 and API as additional methods of inputting voluntary reorganization instructions, and (ii) a footnote directing Participants to the “Automated Instruction Messaging” section for additional information about Automated Instruction Messaging through ISO 20022 messages and APIs.

4. After the “About the Reorganizations Service” section, insert a new section titled “Automated Instruction Messaging.” The section would list: (i) The ATOP actions for ATOP-eligible offers for which Automated Instruction Messaging is available, which would be: Accepting an ATOP-Eligible Offer, Accepting an ATOP-Eligible Offer via Notice of Guaranteed Delivery, Submitting a Cover of Protect, and Puts, (ii) the Automated Instruction Message Types, which are ISO 20002 Corporate Action Instruction (CAIN) and API POST, and (iii) the Automated Response Message Types, which are ISO 20022 Corporate Action Instruction Status Advice (CAIS) and API GET. The section would also include a note stating that all withdrawal and cancellation instructions for ATOP-eligible offers must be performed via PTS/PBS and cannot be instructed via Automated Instruction Message.

5. In the “Instructions/Expirations” section, above the “Important

Considerations” subsection, insert the following warning as a reminder to Participants of their responsibility to monitor the status of their instructions and to take any actions necessary to complete an incomplete transaction: Warning!

Regarding incomplete instructions: An instruction that was submitted via PTS (PTOPTOP, PSOPTOP, PUTS, WARR, RCNV, CERR), PBS (Voluntary Tenders and Exchanges, Rights Subscriptions, Put Option Bonds, Reorg Conversions, CD Early Redemptions, Warrants Subscriptions) or via Automated Instruction Messaging but was not fully processed by-DTC is an incomplete transaction. A Participant has the sole responsibility to monitor its messages and confirm that its instruction was processed and that the quantity of securities that are the subject of its instruction are shown under the contract CUSIP/RRG specified in the instruction. A Participant that submits an incomplete instruction via Automated Instruction Messaging will receive an Automated Response Message indicating a rejection. Neither DTC nor the agent will take action on an incomplete transaction. The Participant is solely responsible for taking the additional processing steps to complete the transactions before expiration cut-off date and time. DTC shall have no responsibility in respect of a Participant’s failure to recognize its instruction as incomplete or to take the steps necessary to complete its transaction. Participants can use the inquiry feature of the aforementioned PTS and PBS functions, as applicable, to identify an incomplete transaction. For instructions submitted via Automated Instruction Messaging, the Automated Response Message will indicate the reason for rejection.

In addition, DTC is proposing to delete other warnings relating to incomplete instructions in connection with ATOP-eligible offers, as they would be redundant with the insertion of the above warning.

6. In the “Instructions/Expirations” section, under the new warning referenced above, insert a note that states that all withdrawal and cancellation instructions must be performed via PTS/PBS.

7. In the “About DTC’s Automated Tender Offer Program (ATOP)” subsection of the “Instructions/Expirations” section, remove the phrases “using the PTS PTOPTOP and PBS Voluntary Tenders and Exchanges or via CCF,” and “by book-entry through PTS PTOPTOP or PBS Voluntary Tenders and

Exchanges, or via CCF,” as it is unnecessary and limiting.

8. In the “Proration of an Offer” section, for accuracy, insert a reference to CA Web as a source to review the position movements representing the unaccepted position.

9. Add a reference to “Automated Instruction Messaging” to the following section headings: “Voluntary Offers by Issuer or Third Party (Processed via PTOPTOP),” “Submitting a Cover of Protect via PTS PTOPTOP or PBS Voluntary Tenders and Exchanges for an ATOP-Eligible Offer,” “Checklist for Submitting a Cover of Protect via PTS PTOPTOP or PBS Voluntary Tenders and Exchanges.”

10. Amend the Guide to reflect that when a Participant uses an Automated Instruction Message, it must check its Automated Response Message, in order to ensure that its transactions were properly processed and recorded, and to note that a Participant could additionally check its Participant Daily Activity Statement and the CA Web.

11. Replace the following paragraph, which appears in the checklists for submitting instructions for ATOP-eligible offers, “Participants that subscribe to the ISO 20022 Instructions Statement Report (CAST) will be able to verify instruction status on the message” with “Participants that submit an Automated Instruction Message must monitor the status of their instruction using the Automated Response Message. Additionally, the CAST message is available to monitor instructed and uninstructed balances.”

12. In the “Accepting an ATOP-Eligible Offer” section, in order to reflect that for an ATOP Offer with (i) an actual expiration time between 6:00 p.m. ET and midnight, the DTC Cut-Off Time would typically be 6:00 p.m. ET, and (ii) an actual expiration time before 5:00 p.m. ET on expiration date, the DTC Cut-Off Time would vary depending on the facts and circumstances of the offer, DTC is proposing to replace the existing paragraph that begins “The dates on which you can accept an offer via PTOPTOP . . .” with the following paragraphs:

“The dates on which you can accept an offer via PTS PTOPTOP, PBS Voluntary Tenders and Exchanges, and Automated Instruction Messaging are specified in the notice about the offer, which you can view via CA Web Announcements, ISO 20022 messaging and PTS RIPS or PBS Reorganizations and Redemptions functions. Unless otherwise specified in the PTS RIPS, PBS Reorganizations and Redemptions or ISO 20022 messaging, PTS PTOPTOP, PBS Voluntary Tenders and Exchanges, and Automated Instruction

Messaging are available on those dates for this purpose. DTC processing cut-off times on the day of expiration typically will be either 5:00 p.m. ET (where the notice of the offer specifies an expiration time of 5:00 p.m. ET on expiration date) or 6:00 p.m. ET (where the notice of the offer specifies an expiration time between 6:00 p.m. ET and midnight on expiration date). Please note that the DTC processing cut-off times for offers that specify an offer expiration time before 5:00 p.m. ET on expiration date will vary depending on the facts and circumstances of the offer.

Note: Participants are reminded that expiration and cutoff time may vary per the terms of the offer. Participants are independently responsible to confirm, per the terms of the offer and announcement, the offer expiration date and time, as well as the applicable DTC processing cut-off time, per the terms of the offer and the announcement.”

13. In the “Checklist for Submitting an Acceptance” section, insert the following language to address how a Participant needs to acknowledge the Letter of Transmittal when it transmits an acceptance via Automated Instruction Messaging:

“Likewise, when you transmit an acceptance via Automated Instruction Messaging, you will be required to acknowledge the Letter of Transmittal required by the offer identified by the contra-CUSIP you specify in your acceptance. The message must contain your acknowledgement. If your message does not contain your acknowledgement, your acceptance will be rejected. By acknowledging the Letter of Transmittal via Automated Instruction Messaging, you agree that (i) you have received, and will be bound by the terms of, the Letter of Transmittal required by the offer identified in the acceptance and (ii) the agreement set forth in the preceding clause (i) may be enforced against you by the Offeror in such offer”.

14. In the “Submitting a Protect for an ATOP-Eligible Offer” section, in order to reflect that for an ATOP Offer with (i) an actual expiration time between 6:00 p.m. ET and midnight, the DTC Cut-Off Time would typically be 6:00 p.m. ET, and (ii) an actual expiration time before 5:00 p.m. ET on expiration date, the DTC Cut-Off Time would vary depending on the facts and circumstances of the offer, DTC is proposing to replace the existing paragraph that begins “The dates on which you can accept an offer by submitting a Notice . . .” with the following paragraphs:

“The dates on which you can accept an offer by submitting a Notice of

Guaranteed Delivery via PTS PTOp, PBS Voluntary Tenders and Exchanges, and Automated Instruction Messaging are specified in the notice about the offer, which you can view via CA Web Announcements, ISO 20022 messaging and PTS RIPS or PBS Reorganizations and Redemptions functions. Unless otherwise specified in the PTS RIPS, PBS Reorganizations and Redemptions or ISO 20022 messaging, PTS PTOp, PBS Voluntary Tenders and Exchanges, and Automated Instruction Messaging are available on those dates for this purpose. DTC processing cut-off times on the day of expiration typically will be either 5:00 p.m. ET (where the notice of the offer specifies an expiration time of 5:00 p.m. ET on expiration date) or 6:00 p.m. ET (where the notice of the offer specifies an expiration time between 6:00 p.m. ET and midnight on expiration date). Please note that the DTC processing cut-off times for offers that specify an offer expiration time before 5:00 p.m. ET on expiration date will vary depending on the facts and circumstances of the offer.

Note: Participants are reminded that expiration and cutoff time may vary per the terms of the offer. Participants are independently responsible to confirm, per the terms of the offer and announcement, the offer expiration date and time, as well as the applicable DTC processing cut-off time, per the terms of the offer and the announcement.”

15. In the “Checklist for Submitting a Protect” section, insert the following language to address how a Participant needs to acknowledge the Notice of Guaranteed Delivery when it transmits an acceptance by Notice of Guaranteed Delivery via Automated Instruction Messaging:

“Likewise, when you transmit an acceptance via Automated Instruction Messaging, you will be required to acknowledge the Notice of Guaranteed Delivery required by the offer identified by the contra-CUSIP you specify in your acceptance. The message must contain your acknowledgement. If your message does not contain your acknowledgement, your acceptance will be rejected. By acknowledging the Notice of Guaranteed Delivery via Automated Instruction Messaging, you agree that (i) you have received, and will be bound by the terms of, the Notice of Guaranteed Delivery required by the offer identified in the acceptance and (ii) the agreement set forth in the preceding clause (i) may be enforced against you by the Offeror in such offer.”

16. In the “Submitting a Cover of Protect via PTS PTOp or PBS Voluntary Tenders and Exchanges for an ATOP-

Eligible Offer,” section, in order to reflect that for an ATOP Offer with (i) an actual expiration time between 6:00 p.m. ET and midnight, the DTC Cut-Off Time would typically be 6:00 p.m. ET, and (ii) an actual expiration time before 5:00 p.m. ET on expiration date, the DTC Cut-Off Time would vary depending on the facts and circumstances of the offer, DTC is proposing to replace the existing paragraph that begins “The dates on which you can submit a cover of protect via PTOp . . .” with the following paragraphs:

“The dates on which you can submit a cover of protect via PTS PTOp, PBS Voluntary Tenders and Exchanges, and Automated Instruction Messaging are specified in the notice about the offer, which you can view via CA Web Announcements, ISO 20022 messaging and PTS RIPS or PBS Reorganizations and Redemptions functions. Unless otherwise specified in the notice, PTS PTOp, PBS Voluntary Tenders and Exchanges, and Automated Instruction Messaging are available on those dates for this purpose. DTC processing cut-off times on the day of expiration typically will be either 5:00 p.m. ET (where the notice of the offer specifies an expiration time of 5:00 p.m. ET on expiration date) or 6:00 p.m. ET (where the notice of the offer specifies an expiration time between 6:00 p.m. ET and midnight on expiration date). Please note that the DTC processing cut-off times for offers that specify an offer expiration time before 5:00 p.m. ET on expiration date will vary depending on the facts and circumstances of the offer.

Note: Participants are reminded that expiration and cutoff time may vary per the terms of the offer. Participants are independently responsible to confirm, per the terms of the offer and announcement, the offer expiration date and time, as well as the applicable DTC processing cut-off time, per the terms of the offer and the announcement.”

17. In the “Checklist for Submitting a Cover of Protect via PTS PTOp or PBS Voluntary Tenders and Exchanges” section:

a. At the end of the first bulleted paragraph under number 6 of the checklist, in order to reflect that the “made” status of an Automated Instruction Message would be confirmed in the Automated Response Message, add the sentence “The Automated Response Message will confirm the “made” status.”

b. Insert the following language to address how a Participant needs to acknowledge the Letter of Transmittal when it transmits a cover of protect via Automated Instruction Messaging:

“Likewise, when you transmit an instruction to cover a protect via Automated Instruction Messaging, you will be required to acknowledge the Letter of Transmittal required by the offer identified by the contra-CUSIP you specify in your instruction. The message must contain your acknowledgement. If your message does not contain your acknowledgement, your instruction will be rejected. By submitting the acknowledgment via Automated Instruction Messaging, you agree that (i) you have received, and will be bound by the terms of, the Letter of Transmittal required by the offer identified in the acceptance and (ii) the agreement set forth in the preceding clause (i) may be enforced against you by the Offeror in such offer.”

18. In the “Submitting a Cover of Protect via PTS PTOF or PBS Voluntary Tenders and Exchanges on Behalf of Another Participant” section, in order to reflect that for an ATOP Offer with (i) an actual expiration time between 6:00 p.m. ET and midnight, the DTC Cut-Off Time would typically be 6:00 p.m. ET, and (ii) an actual expiration time before 5:00 p.m. ET on expiration date, the DTC Cut-Off Time would vary depending on the facts and circumstances of the offer, DTC is proposing to replace the existing paragraph that begins “The dates on which you can submit a cover of protect are specified in the notice about the offer . . .” with the following paragraphs:

“The dates on which you can submit a cover of protect via PTS PTOF and PBS Voluntary Tenders and Exchanges are specified in the notice about the offer, which you can view via CA Web Announcements, ISO 20022 messaging and PTS RIPS or PBS Reorganizations and Redemptions functions. Unless otherwise specified in the PTS RIPS, PBS Reorganizations and Redemptions or ISO 20022 messaging, PTS PTOF and PBS Voluntary Tenders and Exchanges are available on those dates for this purpose. DTC processing cut-off times on the day of expiration typically will be either 5:00 p.m. ET (where the notice of the offer specifies an expiration time of 5:00 p.m. ET on expiration date) or 6:00 p.m. ET (where the notice of the offer specifies an expiration time between 6:00 p.m. ET and midnight on expiration date). Please note that the DTC processing cut-off times for offers that specify an offer expiration time before 5:00 p.m. ET on expiration date will vary depending on the facts and circumstances of the offer.

Note: Participants are reminded that expiration and cutoff time may vary per the terms of the offer. Participants are

independently responsible to confirm, per the terms of the offer and announcement, the offer expiration date and time, as well as the applicable DTC processing cut-off time, per the terms of the offer and the announcement.”

19. In the “Withdrawing an Acceptance of an ATOP-Eligible Offer” section, in order to reflect that for an ATOP Offer with (i) an actual expiration time between 6:00 p.m. ET and midnight, the DTC Cut-Off Time would typically be 6:00 p.m. ET, and (ii) an actual expiration time before 5:00 p.m. ET on expiration date, the DTC Cut-Off Time would vary depending on the facts and circumstances of the offer, DTC is proposing to replace the existing paragraph that begins “The dates on which you can submit a withdrawal of acceptance are specified in the notice about the offer . . .” with the following paragraphs:

“The dates on which you can submit a withdrawal of acceptance via PTS PTOF and PBS Voluntary Tenders and Exchanges are specified in the notice about the offer, which you can view via CA Web Announcements, ISO 20022 messaging and PTS RIPS or PBS Reorganizations and Redemptions functions. Unless otherwise specified in the PTS RIPS, PBS Reorganizations and Redemptions or ISO 20022 messaging, PTS PTOF and PBS Voluntary Tenders and Exchanges are available on those dates for this purpose. DTC processing cut-off times on the day of expiration typically will be either 5:00 p.m. ET (where the notice of the offer specifies an expiration time of 5:00 p.m. ET on expiration date) or 6:00 p.m. ET (where the notice of the offer specifies an expiration time between 6:00 p.m. ET and midnight on expiration date). Please note that the DTC processing cut-off times for offers that specify an offer expiration time before 5:00 p.m. ET on expiration date will vary depending on the facts and circumstances of the offer.

Note: Participants are reminded that expiration and cutoff time may vary per the terms of the offer. Participants are independently responsible to confirm, per the terms of the offer and announcement, the offer expiration date and time, as well as the applicable DTC processing cut-off time, per the terms of the offer and the announcement.”

20. Make ministerial changes to correct typos and omissions and to enhance conformity and readability, including, but not limited to:

a. In the copyright line of the “Important Legal Information” section, replacing “2020” with “2021.”

b. Adding the name of the corresponding PBS function where the equivalent PTS function is referenced.

c. Augmenting mentions of PBS and PTS functions with their full technical names.

d. Removing internal references to other sections within the Guide that are incorrect, no longer relevant, or that no longer exist.

e. Inserting references to the CA Web to correctly reflect that a Participant can check the CA Web, in addition to its Participant Daily Activity Statement and Automated Response Messages, to ensure that its transactions were properly processed and recorded.

f. Inserting references to ISO 20022 messaging and the CA Web to correctly reflect them as sources of ATOP-eligible Offer details.

g. Correcting certain typographical errors.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.¹⁶

The proposed rule change would amend the Guide to provide Participants with the option to use Automated Instruction Messaging for ATOP Offers. As discussed above, the use of Automated Instruction Messaging for ATOP Offers would provide greater straight-through processing, improved accuracy, more efficient integration channels and less processing risk than nonautomated processing.

The proposed rule change would also amend the Guide to adjust and clarify the DTC Cut-Off Times for the submission of instructions in connection with ATOP Offers. Specifically, the proposed rule change would clarify that for ATOP Offers with an actual expiration time between 6:00 p.m. ET and midnight on expiration date, the DTC Cut-Off Time typically is 6:00 p.m. ET, instead of 5:00 p.m. ET. DTC believes that providing Participants with clear directions about the deadlines for the submission of instructions would facilitate the timely submission of instructions and help avoid the submission of instructions outside of DTC. In addition, the proposed rule change would amend the Guide to provide that, with respect to an ATOP Offer with an actual expiration time earlier than 5:00 p.m. ET on expiration date, the DTC Cut-Off Time would vary depending on the particular facts and circumstances of the ATOP Offer. By eliminating the established 1:00 p.m. ET DTC Cut-Off Time for these offers, DTC would have the flexibility to provide Participants with a

¹⁶ 15 U.S.C. 78q-1(b)(3)(F).

DTC Cut-off Time that would be most appropriate to the circumstances, thereby facilitating the timely and orderly submission of instructions.

Finally, DTC believes that the proposed rule change to amend the Guide to make technical and clarifying changes would enhance the clarity and transparency of the Guide. By enhancing the clarity and transparency of the Guide, the proposed rule change would allow Participants to more efficiently and effectively conduct their business in connection with processing reorganization events and associated securities transactions.

Based on the foregoing, DTC believes that the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act, cited above.

(B) Clearing Agency's Statement on Burden on Competition

DTC believes that the proposed rule change to provide Participants with the option to use Automated Instruction Messaging for ATOP Offers would not have any impact on competition.¹⁷ Automated Instruction Messaging would be an optional service that would be available to all Participants in connection with ATOP Offers. In addition, DTC believes that the proposed rule change to amend the Guide to adjust and clarify DTC Cut-Off Times for the submission of ATOP Offer instructions, and to make technical and ministerial changes to the Guide, would not have any impact on competition because it would merely provide Participants with clear directions about the deadlines for the submission of instructions, and would enhance the clarity of the procedures relating to ATOP Offers. In light of the foregoing, DTC does not believe that the proposed rule change would impose a burden on competition.¹⁸

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

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)¹⁹ of the Act and paragraph (f)²⁰ of Rule 19b-4 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 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-DTC-2021-010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.
- All submissions should refer to File Number SR-DTC-2021-010. 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 DTC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-DTC-2021-010 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-14795 Filed 7-12-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92334; File No. SR-NSCC-2021-007]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Proposed Rule Change Relating To Confidential Information, Market Disruption Events, and Other Changes

July 7, 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 June 25, 2021, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. 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 proposed rule change consists of modifications to NSCC's Rules & Procedures ("Rules")³ to (i) revise certain provisions in the Rules relating to the confidentiality of information furnished by applicants, Members and Limited Members (collectively,

²¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Capitalized terms not defined herein are defined in the Rules, available at https://dtcc.com/~media/Files/Downloads/legal/rules/nsccl_rules.pdf.

¹⁷ 15 U.S.C. 78q-1(b)(3)(I).

¹⁸ *Id.*

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f).

“participants”) to NSCC, (ii) require that each participant maintain confidential information furnished by NSCC or its affiliates in confidence and restrict use and disclosure of such information, (iii) add certain officers who are allowed to determine that there is a Market Disruption Event pursuant to Rule 60 and (iv) add a new Rule 60A to address situations in which it is necessary to disconnect a Member, Limited Member, third party service provider, or service bureau due to an imminent threat of harm to NSCC, Members, Limited Members and/or other market participants. Each of the proposed changes is described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The proposed rule change consists of modifications to (i) revise certain provisions in the Rules relating to the confidentiality of information furnished by participants to NSCC, (ii) require that each participant maintain confidential information furnished by NSCC or its affiliates in confidence and restrict use and disclosure of such information, (iii) add certain officers who are allowed to determine that there is a Market Disruption Event pursuant to Rule 60 and (iv) add a new Rule 60A to address situations in which it is necessary to disconnect a Member, Limited Member, third party service provider, or service bureau due to an imminent threat of harm to NSCC, Members, Limited Members and/or other market participants. Each of the proposed changes is described in greater detail below.

(i) NSCC Confidentiality Requirements

Section 1.C. of Rule 2A⁴ and Section 3 of Rule 15⁵ each contain provisions relating to confidentiality of information furnished by participants to NSCC (collectively, the “NSCC Confidentiality Requirements”). The NSCC Confidentiality Requirements provide that such furnished information will be held by NSCC in the same degree of confidence as may be required by law or the rules and regulations of the appropriate regulatory body having jurisdiction over the participant. NSCC is proposing to update the NSCC Confidentiality Requirements because such provisions (i) may result in unequal treatment of participants due to differing laws or regulations of regulatory bodies, (ii) may result in a potential conflict of laws where rules or regulations governing a regulatory body of a participant differ from the laws applicable to NSCC, or a participant has multiple regulatory bodies whose rules conflict, (iii) are burdensome as they require NSCC to track the rules and regulations of each regulatory body of its participants, and ensure that information provided by participants to NSCC is held in confidence to the same degree as it is held by such regulatory bodies and (iv) are unnecessary as NSCC has sufficient protections in place relating to protection and confidentiality of participant data.

The regulatory bodies that have jurisdiction over participants differ by participant depending on certain criteria of each participant, including the type of entity of the participant, where the participant was organized, the types of businesses in which the participant engages and where the participant is doing business. In addition, many participants are regulated by more than one regulatory body. As a result, a requirement to maintain confidentiality standards for information provided by a participant based on the regulatory body or bodies that regulate such participant result in varying standards of confidentiality for participants that are regulated by different regulatory bodies. Such varying standards may result in unequal treatment of participants due to differing laws or regulations of the regulatory body or bodies governing such participants. In addition, such

⁴ Section 1.C. of Rule 2A, *supra* note 3. Rule 2A relates to initial membership requirements including information that NSCC may require applicants to furnish to become Members or Limited Members of NSCC.

⁵ Section 3 of Rule 15, *supra* note 3. Rule 15 relates to assurances of financial responsibility and operational capability including information that NSCC may require Members or applicants to furnish.

varying standards may result in a potential conflict of laws where rules or regulations governing a regulatory body of a participant differ from the laws applicable to NSCC or an entity that has multiple regulatory bodies whose rules conflict.

NSCC believes that it is unnecessarily burdensome to determine the rules and regulations of each of the regulatory bodies that regulate its participants. Such regulatory bodies include numerous U.S. federal and state regulators as well as foreign national, state and local regulators. NSCC proposes revising the language in the NSCC Confidentiality Requirements to maintain one confidentiality standard for all participants rather than maintaining potentially different confidentiality standards for participants based on the various, unrelated regulatory bodies regulating such participants. NSCC is proposing to replace the existing language in the NSCC Confidentiality Requirements with language that would provide that NSCC will hold non-public information furnished pursuant to those Rules in confidence as may be required under the law or the rules and regulations applicable to NSCC that relate to the confidentiality of records. Such laws, rules and regulations would include national, state and foreign laws governing confidentiality of data that are applicable to NSCC in connection with its collection and disclosure of data.

NSCC believes that the rules and regulations applicable to NSCC governing the use and disclosure of confidential information provide standards that are representative of those of the various regulatory bodies governing its participants. As a result, NSCC does not believe that the proposed rule change relating to the NSCC Confidentiality Requirements would result in any change to NSCC's practices relating to data protection and confidentiality of information provided by participants.

(ii) Participant Confidentiality Requirements

Historically, NSCC has generally not provided, nor been requested to provide, information that contains confidential or proprietary information of NSCC or its affiliates to its participants except for information necessary for participants and their service providers and service bureaus to connect to NSCC and to participate in the services that NSCC offers to its Members and Limited Members. While certain information is protected by intellectual property rights of NSCC and

its affiliates under applicable intellectual property laws, such as copyright laws and trademark laws, the Rules do not include any express obligations for participants to protect confidential information received by them from NSCC or its affiliates.

In connection with the development of cyber and information security programs pursuant to applicable regulatory requirements by participants, NSCC and its parent company, The Depository Trust & Clearing Corporation (“DTCC”), have received an increasing number of requests from participants for confidential and proprietary information of NSCC and DTCC.⁶ This includes, for example, information regarding DTCC’s network operations and data security practices, legal settlements, and other information. Additionally, in the event there is a cyber incident relating to a participant, NSCC or DTCC may be requested to disclose confidential information regarding its cyber threat indicators, sources of cyber threat information, or other information and actions taken related to a cyber event.

In order to provide for contractual protections for such confidential information of DTCC, NSCC and DTCC’s other subsidiaries, NSCC is proposing to add provisions to the Rules that would require participants to maintain confidential information of NSCC and its affiliates that NSCC provides to such participants in confidence and not to disclose such confidential information except as necessary to perform such participant’s obligations under NSCC’s Rules or as otherwise required by applicable law (“Participant Confidentiality Requirements”). The Participant Confidentiality Requirements would provide that in the event of a breach of the Participant Confidentiality Requirements, NSCC or DTCC would be entitled to seek any temporary or permanent injunctive or other equitable relief in addition to any monetary damages under the Rules. In addition, as with any failure to comply with its Rules, NSCC would have the ability to impose other disciplinary proceedings or restrictions on access to services as provided in the Rules for failure to comply with the Participant Confidentiality Requirements.

⁶ DTCC provides a set of core business processes for NSCC and DTCC’s other subsidiaries, including the technology systems and networks that provide connectivity between NSCC and its participants and that provide the ability of NSCC to provide the services as required under its Rules. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides relevant services to NSCC and DTCC’s other subsidiaries.

(iii) Market Disruption Events

Rule 60 (Market Disruption and Force Majeure)⁷ (the “Force Majeure Rule”) contains provisions that identify the events or circumstances that would be considered a Market Disruption Event, including, for example, events that lead to the suspension or limitation of trading or banking in the markets in which NSCC operates, or the unavailability or failure of any material payment, bank transfer, wire or securities settlement systems.⁸ Under the Force Majeure Rule, during the pendency of a Market Disruption Event, NSCC would be entitled to (i) suspend the provision of any or all services and (ii) take, or refrain from taking, or require Members and Limited Members to take, or refrain from taking, any actions NSCC considers appropriate to address, alleviate, or mitigate the event and facilitate the continuation of NSCC’s services as may be practicable.⁹

Section 2 of the Force Majeure Rule provides that the Board of Directors may determine the existence of a Market Disruption Event and the actions to be taken in response thereto.¹⁰ However, if the Board of Directors is unable to convene, the Force Majeure Rule provides that certain officers may make such determination, on an interim basis, which determination is then ratified, modified or rescinded as soon as practicable by the Board of Directors. The officers that may make such determination are all senior executive officers of NSCC: Chief Executive Officer, Chief Financial Officer, Group Chief Risk Officer and General Counsel.

The proposed rule change would add two senior executive officers of NSCC, the Chief Information Officer and the Head of Clearing Agency Services, to the list of officers that could make such determination if the Board of Directors is unable to convene. These two officers, like the other senior executive officers currently listed in the Rules, maintain senior executive level positions at NSCC, oversee divisions of NSCC, and hold positions at NSCC that would provide them a necessary global view into NSCC’s operations and systems to enable them to determine the existence of a Market Disruption Event in the event that the Board of Directors is unable to convene. Adding these two additional officers would facilitate NSCC’s ability to implement its emergency procedures in the event of a Market Disruption Event.

⁷ Rule 60, *supra* note 3.

⁸ *Id.*

⁹ *Id.*

¹⁰ Section 2 of Rule 60, *id.*

(iv) Systems Disconnect: Threat of Significant Impact to NSCC’s Systems

The proposed rule change would add a new Rule 60A (Systems Disconnect: Threat of Significant Impact to the Corporation’s Systems) (“Systems Disconnect Rule”) that would address situations in which NSCC determines it is necessary for NSCC to disconnect a single or limited number of Members, Limited Members, or third party service providers or service bureaus used by Members or Limited Members to connect to NSCC¹¹ (collectively, “DTCC Systems Participants”) from NSCC’s systems or network due to an imminent threat of harm to NSCC’s or DTCC’s systems. The imminent threat could be the result of a system disruption or cyber incident applicable to the DTCC Systems Participants. This would allow DTCC to work with the affected participants while protecting NSCC, its systems and its other participants.

The proposed Systems Disconnect Rule would be structured similarly to the Force Majeure Rule. The Systems Disconnect Rule would address NSCC’s authority to take certain actions upon the occurrence, and during the pendency, of a Major Event. A “Major Event” would be defined as the happening of one or more Systems Disruption(s) (as defined below) that is reasonably likely to have a significant impact on NSCC’s operations, including the DTCC Systems (as defined below), that affect the business, operations, safeguarding of securities or funds, or physical functions of NSCC, Members, Limited Members, and/or other market participants. “Systems Disruption” would be defined as the unavailability, failure, malfunction, overload, or restriction (whether partial or total) of a DTCC Systems Participant’s systems that disrupts or degrades the normal operation of such DTCC Systems Participant’s systems; or anything that impacts or alters the normal communication or the files that are received, or information transmitted, to or from the DTCC Systems. “DTCC Systems” would be defined as the systems, equipment and technology networks of DTCC, NSCC and/or their Affiliates,¹² whether owned, leased, or licensed, software, devices, IP addresses

¹¹ Some Members and Limited Members use third parties to connect to NSCC’s systems and/or to send data to NSCC and receive data from NSCC on the Member’s or Limited Member’s behalf. Such third parties are referred to as “service providers” or “service bureaus” herein.

¹² Affiliate is defined in Rule 1 and is intended to cover DTCC and DTCC’s other subsidiaries that use shared systems with NSCC. Rule 1, *supra* note 3. See description of the shared systems of DTCC, NSCC and DTCC’s other subsidiaries, *supra* note 6.

or other addresses or accounts used in connection with providing the services set forth in the Rules, or used to transact business or to manage the connection with NSCC.

The proposed Systems Disconnect Rule would allow NSCC to mitigate the effect of such events by facilitating the continuity of services (or, if deemed necessary, the temporary suspension of services). To that end, under the proposed Systems Disconnect Rule, NSCC would be entitled, during the pendency of a Major Event, to (1) disconnect a DTCC Systems Participant's systems from the DTCC Systems, (2) suspend the receipt and/or transmission of files or communications to or from the DTCC Systems Participant to the DTCC Systems and/or (3) take, or refrain from taking, or require a DTCC Systems Participant to take or refrain from taking, any actions that NSCC considers appropriate to prevent, address, correct, mitigate or alleviate the Major Event and facilitate the continuation of services as may be practicable and, in that context, issue instructions to the DTCC Systems Participant.

The proposed Systems Disconnect Rule would define the governance procedures for how NSCC would determine whether, and how, to implement the provisions of the rule. A determination that a Major Event has occurred could be made by the same officers with delegated authority under the Force Majeure Rule as discussed above (an "Officer Major Event Action"). Following this determination, any management committee on which all of the foregoing officers serve would convene, and NSCC would convene a Board of Directors meeting as soon as practicable thereafter, and in any event within five Business Days following such determination, in each case, to ratify, modify, or rescind the Officer Major Event Action. The proposed Systems Disconnect Rule would require Members and Limited Members to notify NSCC immediately upon becoming aware of a Major Event, and, likewise, would require NSCC to promptly notify the DTCC Systems Participant(s) of any action NSCC takes or intends to take with respect to such DTCC Systems Participant(s) pursuant to the proposed rule.

Finally, the Systems Disconnect Rule would address certain miscellaneous matters including: (i) A limitation of liability for any failure or delay in performance, in whole or in part of NSCC's obligations under the Rules, arising out of or related to a Major Event, (ii) a statement that the power of NSCC to take any action pursuant to the

Systems Disconnect Rule also includes the power to repeal, rescind, revoke, amend or vary such action, (iii) a statement that the powers of NSCC pursuant to the Systems Disconnect Rule shall be in addition to and not in derogation of, authority granted elsewhere in the Rules to take action as specified therein, (iv) a requirement that Members and Limited Members shall keep any DTCC Confidential Information (as defined below) provided to them by NSCC and/or in connection with a Major Event confidential and (v) a statement that in the event of any conflict between the provisions of the Systems Disconnect Rule and any other Rules or Procedures, the provisions of the Systems Disconnect Rule would prevail.

(v) Proposed Rule Changes

The proposed rule change would amend the Rules to make the following changes to implement the changes discussed above:

NSCC Confidentiality Requirements Changes

The proposed rule change would amend the NSCC Confidentiality Requirements in Section 1.C. of Rule 2A¹⁵ and Section 3 of Rule 15¹⁴ to state as follows:

Any non-public information furnished to the Corporation pursuant to this Rule shall be held in confidence as may be required under the laws, rules and regulations applicable to the Corporation that relate to the confidentiality of records.

As discussed above, the proposed language is intended to provide one standard that NSCC would apply uniformly to all participants, which assures participants that such information would be held in confidence with appropriate controls. NSCC would add "non-public" when describing the information that is subject to the NSCC Confidentiality Requirements to make it clear that such requirements would only apply to information that is not public in both Section 1.C. of Rule 2A and Section 3 of Rule 15. NSCC would also amend a sentence in Addendum L that references the NSCC Confidentiality Requirements set forth in Rule 15 to reflect the proposed updated language.

Section 1.C. of Rule 2A would also include language relating to Participant Confidentiality Requirements as described below.

Participant Confidentiality Requirements

In order to provide for Participant Confidentiality Requirements, NSCC would add provisions in Section 1.C. of Rule 2A¹⁵ (with respect to applicants) and a new Section 5 of Rule 2B¹⁶ (with respect to Members and Limited Members) to state that each participant shall maintain DTCC Confidential Information in confidence to the same extent and using the same means it uses to protect its own confidential information, but no less than a reasonable standard of care, and shall not use DTCC Confidential Information or disclose DTCC Confidential Information to any third party except as necessary to perform its obligations under the Rules or as otherwise required by applicable law. NSCC would add a new definition of DTCC Confidential Information in Rule 1¹⁷ to provide that "DTCC Confidential Information" would mean all non-public information provided by DTCC and/or NSCC that (i) is marked or otherwise identified in writing prior to disclosure to the recipient as confidential, (ii) is designated by DTCC or NSCC as confidential, or (iii) the recipient knows or, under the circumstances surrounding disclosure, ought to reasonably know is confidential. NSCC would also add a definition of DTCC in Rule 1 and remove a corresponding definition in Rule 42¹⁸ since it would be defined in Rule 1.

NSCC would also add a statement in each provision relating to Participant Confidentiality Requirements that each participant acknowledges that a breach of its confidentiality obligations under the Rules may result in serious and irreparable harm to NSCC and/or DTCC for which there is no adequate remedy at law. In the event of such a breach by the participant, NSCC and/or DTCC would be entitled to seek any temporary or permanent injunctive or other equitable relief in addition to any monetary damages. In addition, NSCC would re-number the existing Section 5 of Rule 2B to Section 6 to reflect the addition of the new Section 5.

Force Majeure Rule Officer Additions

The proposed rule change would add the Chief Information Officer and the Head of Clearing Agency Services to the list of officers that could make a determination of a Market Disruption

¹⁵ Section 1.C. of Rule 2A, *supra* note 3.

¹⁶ Rule 2B, *supra* note 3.

¹⁷ Rule 1, *supra* note 3.

¹⁸ Rule 42, *supra* note 3.

¹³ Section 1.C. of Rule 2A, *supra* note 3.

¹⁴ Section 3 of Rule 15, *supra* note 3.

Event if the Board of Directors is unable to convene in Rule 60.¹⁹

Systems Disconnect Rule

The proposed rule change would add a new Rule 60A entitled “Systems Disconnect: Threat of Significant Impact to the Corporation’s Systems” that would address situations in which NSCC determines it is necessary for NSCC to disconnect a DTCC Systems Participant or DTCC Systems Participants from NSCC’s systems or network due to an imminent threat of harm to NSCC’s or DTCC’s systems consistent with the description above. The proposed Systems Disconnect Rule would include new definitions for “DTCC Systems,” “DTCC Systems Participant,” “Major Event” and “Systems Disruption” consistent with the descriptions of the Systems Disconnect Rule above.

2. Statutory Basis

NSCC believes that the proposal is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered clearing agency. In particular, NSCC believes that each of the proposed rule changes is consistent with Section 17A(b)(3)(F) of the Act,²⁰ and Rules 17Ad–22(e)(1) and (e)(21)²¹ promulgated under the Act. In addition, NSCC believes that the proposed changes to add the two senior executive officers in the Force Majeure Rule and to add the proposed Systems Disconnect Rule are consistent with Rules 17Ad–22(e)(2) and (e)(17) under the Act.²²

Section 17A(b)(3)(F)

Section 17A(b)(3)(F) of the Act²³ requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible, and to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.

NSCC believes that the proposed changes revising the NSCC Confidentiality Requirements and adding the Participant Confidentiality Requirements are each consistent with this provision of the Act. The proposed revisions to the NSCC Confidentiality Requirements are consistent with this

provision because the proposed revisions would provide a clear and consistent standard relating to how NSCC holds the information furnished by participants pursuant to Rule 2A²⁴ and Rule 15.²⁵ The confidential information that NSCC receives pursuant to Rule 2A and Rule 15 is used by NSCC to determine whether to admit a participant as a Member or Limited Member, to continue to allow such participant to be a Member or Limited Member, or to better understand the risks relating to each participant. Providing a clear and consistent standard would facilitate this process by allowing participants to better understand NSCC’s obligations with respect to such information and providing a uniform obligation for NSCC with respect to such information. NSCC believes that facilitating the ability of NSCC to evaluate participants would promote the prompt and accurate clearance and settlement of securities transactions by NSCC. As such, NSCC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act.²⁶

NSCC also believes that the proposed rule change adding the Participant Confidentiality Requirements is consistent with this provision of the Act because the proposed revisions to the Participant Confidentiality Requirements would provide a clear and consistent contractual obligation for participants who are requesting confidential information from NSCC. Having clear and consistent Rules would help participants to better understand their rights and obligations regarding NSCC’s clearance and settlement services. The information requested by participants that would be subject to the Participant Confidentiality Requirements would be used by participants to determine whether to participate in NSCC’s services, NSCC system requirements and NSCC system safeguards. NSCC believes that when Members and Limited Members better understand their rights and obligations regarding NSCC’s clearance and settlement services, they can better act in accordance with the Rules. NSCC believes that better enabling Members and Limited Members to comply with the Rules would promote the prompt and accurate clearance and settlement of securities transactions by NSCC. As such, NSCC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act.²⁷

NSCC believes that the proposed changes to add the two officers to make a determination of a Market Disruption Event and to add the Systems Disconnect Rule are also consistent with this provision of the Act because those changes would enhance and streamline NSCC’s ability to take necessary actions in the event of a Market Disruption Event or a Major Event. Improving the ability of NSCC to react to a Market Disruption Event or a Major Event would allow NSCC to protect its participants and their ability to promptly and accurately clear and settle securities transactions, and allow NSCC to safeguard securities and funds that are in its custody or control. In particular, allowing two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to NSCC while maintaining proper risk controls and improve the ability of NSCC to act in the event of a Market Disruption Event. Also, providing for the ability of NSCC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect NSCC and its participants would, in each case, provide additional tools for NSCC in the event of a Major Event.

Improving the governance around the determination of a Market Disruption Event, and the implementation of procedures allowing NSCC to disconnect a DTCC Systems Participant or DTCC Systems Participants from NSCC’s systems or network due to an imminent threat of harm, would improve NSCC’s ability to address and minimize losses to NSCC and its participants. Risks, threats and potential vulnerabilities due to a Market Disruption Event or a Major Event could impact NSCC’s ability to clear and settle securities transactions, or to safeguard the securities and funds which are in its custody or control or for which it is responsible. In addition, providing governance around the ability to disconnect a DTCC Systems Participant that is having a systems disruption that could disrupt the ability of NSCC or other DTCC Systems Participants from using NSCC’s systems would remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. Although disconnecting or limiting the service of a DTCC Systems Participant

¹⁹ Rule 60, *supra* note 3.

²⁰ 15 U.S.C. 78q–1(b)(3)(F).

²¹ 17 CFR 240.17Ad–22(e)(1) and (e)(21).

²² 17 CFR 240.17Ad–22(e)(2) and (e)(17).

²³ 15 U.S.C. 78q–1(b)(3)(F).

²⁴ Rule 2A, *supra* note 3.

²⁵ Rule 15, *supra* note 3.

²⁶ 15 U.S.C. 78q–1(b)(3)(F).

²⁷ *Id.*

in the event of a Major Event would likely be an impediment to such DTCC Systems Participant, improving NSCC's ability to address and minimize losses to NSCC and its participants, and reducing risks, threats and potential vulnerabilities due to a Major Event that could impact NSCC's ability to clear and settle securities transactions, or to safeguard the securities and funds which are in its custody or control or for which it is responsible, would be consistent with Section 17A(b)(3)(F) of the Act.²⁸

Therefore, by implementing tools that would help to mitigate these risks, NSCC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible, and remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.²⁹

Rule 17Ad-22(e)(1)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(1) promulgated under the Act,³⁰ which requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities in all relevant jurisdictions.

Establishing clear and consistent rules for each participant with respect to the NSCC Confidentiality Requirements would allow NSCC to maintain one confidentiality standard for all participants rather than maintaining potentially different confidentiality standards for participants based on the various, unrelated regulatory bodies governing such participants. In addition, setting forth a clear contractual obligation relating to Participant Confidentiality Requirements would enhance the understanding of the participants receiving information from NSCC and allow NSCC to treat participants equally with respect to how the information furnished to participants should be protected by the participants.

Adding the two officers to make a determination of a Market Disruption Event and adding the Systems Disconnect Rule are also consistent with

Rule 17Ad-22(e)(1) under the Act because those changes would describe the circumstances under which NSCC could take actions in the event of a Market Disruption Event or a Major Event that are necessary to protect NSCC and its participants. Providing clear guidelines with respect to Market Disruption Events and Major Events would allow participants to understand the rights and obligations of the participants in the event of a Market Disruption Event or a Major Event.

Therefore, by establishing uniform and clear standards with respect to its receipt and furnishing of confidential information, and by providing clear rights and obligations of NSCC and its participants with respect to Market Disruption Events and Major Events, NSCC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(1) promulgated under the Act.³¹

Rule 17Ad-22(e)(21)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(21) promulgated under the Act,³² which requires NSCC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves. The proposed rule change would streamline the NSCC Confidentiality Requirements by providing that NSCC would apply one standard for all participants relating to confidential information sent to NSCC by participants, which would enhance (i) efficiency by avoiding applying varying standards of confidentiality based on the rules and regulations of the varying regulatory bodies that regulate the participants, and (ii) effectiveness by reducing potential conflicts of laws and providing equal treatment to participants relating to such confidential information.

The addition of the Participant Confidentiality Requirements would also provide a uniform and easily discernable requirement for all participants with respect to confidential information provided by NSCC allowing NSCC to provide necessary information to such participants in a safe and efficient manner. Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to NSCC while maintaining proper risk

controls and improve the ability of NSCC to act quickly, efficiently and effectively in a Market Disruption Event to address and minimize losses. Also, providing for the ability of NSCC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect NSCC and its participants would, in each case, provide additional tools for NSCC in the event of a Major Event and improve NSCC's ability to act quickly, efficiently and effectively in the event of a Major Event to address and minimize losses.

Therefore, by establishing a more efficient and effective process for the treatment of confidential language, and establishing procedures designed to improve NSCC's ability to act quickly, efficiently and effectively in the event of a Market Disruption Event and a Major Event, NSCC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(21) promulgated under the Act.³³

Rule 17Ad-22(e)(2)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(2) promulgated under the Act,³⁴ which requires NSCC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and that specify clear and direct lines of responsibility.

Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to NSCC while maintaining proper risk controls, and improve the ability of NSCC to act quickly, efficiently and effectively in a Market Disruption Event and mitigate any impact from such Market Disruption Event. Adding these officers to the governance procedures relating to a determination of a Market Disruption Event would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Market Disruption Event, consistent with Rule 17Ad-22(e)(2) under the Act.³⁵

Adding the governance procedures relating to making a determination of a Major Event in the Systems Disconnect

²⁸ *Id.*

²⁹ *Id.*

³⁰ 17 CFR 240.17Ad-22(e)(1).

³¹ *Id.*

³² 17 CFR 240.17Ad-22(e)(21).

³³ *Id.*

³⁴ 17 CFR 240.17Ad-22(e)(2).

³⁵ *Id.*

Rule is also consistent with Rule 17Ad–22(e)(2) promulgated under the Act.³⁶ Identifying the officers that have the ability to determine if there is a Major Event, and providing for the ability of any management committee on which all of such officers serve and the Board of Directors to ratify, modify or rescind any determination of a Major Event by an officer would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Major Event, consistent with Rule 17Ad–22(e)(2).³⁷

Rule 17Ad–22(e)(17)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad–22(e)(17)(i) promulgated under the Act,³⁸ which requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to manage the covered clearing agency's operational risks by identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls.

Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to NSCC while maintaining proper risk controls and improve the ability of NSCC to act quickly, efficiently and effectively in a Market Disruption Event and mitigate any impact from such Market Disruption Event. Also, providing for the ability of NSCC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect NSCC and its participants would, in each case, provide additional tools for NSCC in the event of a Major Event and improve NSCC's ability to act quickly, efficiently and effectively in the event of a Major Event and mitigate any impact from such Major Event.

Therefore, by providing clear, efficient procedures of NSCC and its participants with respect to Market Disruption Events and Major Events that help identify and mitigate operational risks, NSCC believes that the proposed rule change is consistent with the

requirements of Rule 17Ad–22(e)(17)(i) promulgated under the Act.³⁹

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed changes relating to the NSCC Confidentiality Requirements would have any impact on competition. These changes would provide one standard for how NSCC treats participant information furnished subject to the NSCC Confidentiality Requirements but would not affect the information that the participants are required to provide or affect the manner in which the participants must provide the information. As such, NSCC believes these proposed rule changes would not have any impact on competition.

NSCC does not believe the proposed changes relating to adding Participant Confidentiality Requirements would have any impact on competition. Although the addition of the Participant Confidentiality Requirements would be adding obligations on participants with respect to how they treat confidential or proprietary information of NSCC or its affiliates, such obligations would be minimal because NSCC would only require that such participants hold such confidential information using the same means they use to protect their own confidential information but not less than a reasonable standard of care. The use of this standard would protect NSCC by providing a clear legal obligation to protect such information but would not be burdensome or expensive for participants, and therefore NSCC believes that it would not have any impact on competition.

NSCC does not believe the changes relating to adding the two officers to make a determination of a Market Disruption Event would have any impact on competition. The proposed rule change would add two senior executive officers of NSCC, the Chief Information Officer and the Head of Clearing Agency Services, to the list of officers that could make a determination of a Market Disruption Event if the Board of Directors is unable to convene. Such addition would provide additional officers who could determine whether there is a Market Disruption Event but would not otherwise affect the rights of Members or Limited Members or NSCC in the determination of a Market Disruption Event or if a Market Disruption Event is declared. Therefore, NSCC does not believe that the addition of the two officers would have any impact on competition.

NSCC does not believe that the changes relating to adding the Systems Disconnect Rule would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act.⁴⁰ To the extent that NSCC determines that there is a Major Event, it could take or refrain from taking actions, or require participants to take or refrain from taking actions, that could burden competition because such requirements could cause participants to incur additional costs, allow NSCC to suspend services or communications, or disconnect a DTCC Systems Participant from the DTCC Systems. NSCC believes such burden on competition could be significant but would be both necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act,⁴¹ for the reasons described below.

NSCC believes that the proposed changes to add the Systems Disconnect Rule are necessary in furtherance of the purposes of Section 17A(b)(3)(F) of the Act,⁴² and Rules 17Ad–22(e)(1), (e)(2), (e)(17) and (e)(21) promulgated under the Act.⁴³ The proposed changes to add the Systems Disconnect Rule would (i) improve the ability of NSCC to react to a Major Event allowing NSCC to protect itself and its participants and their ability to promptly and accurately clear and settle securities transactions, and allow NSCC to safeguard securities and funds that are in its custody or control, consistent with the requirements of Section 17A(b)(3)(F) of the Act,⁴⁴ (ii) provide clear guidelines with respect to Major Events that would allow participants to understand the rights and obligations of the participants and NSCC in the event of a Major Event, consistent with Rule 17Ad–22(e)(1) promulgated under the Act,⁴⁵ (iii) identify the officers that have the ability to determine if there is a Major Event, and provide for the ability of any management committee on which all of such officers serve, and the Board of Directors, to ratify, modify or rescind any determination of a Major Event by an officer, which would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Major Event, consistent with Rule 17Ad 22(e)(2)

⁴⁰ 15 U.S.C. 78q–1(b)(3)(I).

⁴¹ *Id.*

⁴² 15 U.S.C. 78q–1(b)(3)(F).

⁴³ 17 CFR 240.17Ad–22(e)(1), (e)(2), (e)(17) and (e)(21).

⁴⁴ 15 U.S.C. 78q–1(b)(3)(F).

⁴⁵ 17 CFR 240.17Ad–22(e)(1).

³⁶ *Id.*

³⁷ *Id.*

³⁸ 17 CFR 240.17Ad–22(e)(17)(i).

³⁹ *Id.*

promulgated under the Act,⁴⁶ (iv) improve the ability of NSCC to act quickly, efficiently and effectively in the event of a Major Event, and mitigate any impact from such event by providing clear, efficient procedures of NSCC and its participants with respect to such event, consistent with the requirements of Rule 17Ad-22(e)(17)(i) promulgated under the Act⁴⁷ and (v) establish procedures designed to improve NSCC's ability to act quickly, efficiently and effectively in the event of a Major Event, consistent with the requirements of Rule 17Ad-22(e)(21) promulgated under the Act.⁴⁸

In addition, NSCC believes that the proposed changes to add the Systems Disconnect Rule are appropriate in furtherance of the Act. Such changes have been designed to improve the ability of NSCC to act quickly, efficiently and effectively in the event of a Major Event, and mitigate any impact from such event while also providing the Members and Limited Members clear guidelines with respect to such event to allow participants to understand their rights and obligations. Such changes have also been designed to apply uniformly to all Members and Limited Members in the event of a Major Event and should not affect NSCC's day-to-day operations under normal circumstances, or in the management of a typical Member or Limited Member default scenario or non-default event.

Therefore, NSCC does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.⁴⁹

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which

the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NSCC-2021-007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-NSCC-2021-007. 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 NSCC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-NSCC-2021-007 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁰

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-14791 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92340; File No. SR-FICC-2021-005]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the FICC Government Securities Division Rulebook, FICC Mortgage-Backed Securities Division Clearing Rules, and FICC Mortgage-Backed Securities Division EPN Rules

July 7, 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 June 30, 2021, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(4) thereunder.⁴ 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 proposed rule change of FICC consists of modifications to the FICC Government Securities Division ("GSD") Rulebook ("GSD Rules"), the FICC Mortgage-Backed Securities Division ("MBSD") Clearing Rules ("MBSD Rules") and the FICC MBSD EPN Rules ("EPN Rules," and together with the GSD Rules and the MBSD Rules, the "Rules")⁵ in order to (i)

⁵⁰ 17 CFR 200.30-3(a)(12).

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).

⁵ Capitalized terms used herein and not defined shall have the meanings assigned to such terms in the GSD Rules, MBSD Rules and EPN Rules, as applicable, available at <http://www.dtcc.com/legal/rules-and-procedures.aspx>.

⁴⁶ 17 CFR 240.17Ad-22(e)(2).

⁴⁷ 17 CFR 240.17Ad-22(e)(17)(i).

⁴⁸ 17 CFR 240.17Ad-22(e)(21).

⁴⁹ 15 U.S.C. 78q-1(b)(3)(I).

correct or clarify the use of certain defined terms in the Rules, (ii) make certain clarifications and corrections in the Rules, and (iii) make certain technical changes to the Rules, each as described in more detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

FICC is proposing to (i) correct the use of certain defined terms in the Rules, (ii) make certain clarifications and corrections in the Rules, and (iii) make certain technical changes to the Rules, each as described in more detail below.

(i) Proposal To Correct or Clarify the Use of Certain Defined Terms in the Rules

A. Proposal To Delete Terms That Are no Longer Used in the Rules

FICC is proposing to remove the following defined terms and related descriptions, as applicable, in the Rules:

- “GCF Securities Account” in GSD Rule 1 and the phrase “and for which the Corporation establishes a GCF Securities Account” in the defined term “GCF Clearing Agent Bank” in GSD Rule 1 because these provisions relate to the interbank service of the GCF Repo Service, which FICC does not expect to reinstitute.⁶

⁶ In 2016, the Commission approved FICC's proposed rule change to suspend the interbank service of the GCF Repo Service. The GCF Repo Service has operated on both an “interbank” and “intrabank” basis. “Interbank” means that the two GCF Repo Participants, which have been matched in a GCF Repo transaction, each clear at a different clearing bank. See Securities Exchange Act Release No. 78206 (June 30, 2016), 81 FR 44388 (July 7, 2016) (SR-FICC-2016-002).

“Intrabank” means that the two GCF Repo Participants, which have been matched in a GCF Repo transaction, clear at the same clearing bank. FICC does not expect to reinstitute the interbank service of the GCF Repo Service at this time and removed all references to this service from the GSD Rules in 2020. See Securities Exchange Act Release No. 88766 (April 29, 2020), 85 FR 26747 (May 5, 2020) (SR-FICC-2020-005) (“FICC Clean-Up Changes Filing”).

- “and Clearing Fund Funds-Only Settlement Amount” in the defined term “Opening Balance” in GSD Rule 1 because “Clearing Fund Funds-Only Settlement Amount” is no longer a defined term in the GSD Rules.⁷

• the defined term “Direct Transaction” in MBSD Rule 1 because this defined term is no longer used in the MBSD Rules (it was used in a previous version of the rules relating to loss allocation).

• the defined term “Eligible Letter of Credit” in MBSD Rule 1 because this defined term is no longer used in the MBSD Rules (it is no longer a required form of Clearing Fund).

• the defined term “TBA Comparison” from MBSD Rule 1 because this defined term is not used in the MSBD Rules and is also duplicative (it has the same definition as the defined term “Trade Comparison”).

• the defined term “GCF Collateral Excess Account” in MBSD Rule 1 because this is a typographical error and was inadvertently included in the MBSD Rules. GCF Collateral Excess Account is only relevant to the GSD Rules, not the MBSD Rules.

B. Proposal To Revise References To Reflect the Existing Defined Terms and Related Changes

FICC is proposing to capitalize references to the following words to reflect the existing defined terms in their respective Rules:

- “registered clearing agencies” in GSD Rule 36 and EPN Article V, Rule 10
- “clearing agency” in EPN Article V, Rule 14

As described above, because FICC is proposing to capitalize the references to registered clearing agencies and clearing agencies in the EPN Rules in order to be consistent with the GSD Rules and MSBD Rules, FICC is also proposing to add the defined terms “Registered Clearing Agency” and “Clearing Agency to EPN Article I, Rule 1 to enhance clarity.

FICC is also proposing to revise “Securities and Exchange Commission” to “SEC” in GSD Rule 36 to reflect the existing defined term.

In addition, FICC is proposing to add “EPN” before the references to “Rules” in EPN Article V, Rule 10 to reflect the existing defined term.

⁷ Most of the references to the term “Clearing Fund Funds-Only Settlement Amount” were deleted in the FICC Clean-Up Changes Filing because this is an outdated Clearing Fund component and should have been deleted when GSD moved to a VaR-based Clearing Fund methodology. See FICC Clean-up Changes Filing, *supra* note 6.

C. Proposal To Revise Capitalized Terms To Reflect That They Are Not Defined Terms

FICC is proposing to revise the references from “Website” to “website” in Section 2 of GSD Rule 3 because “Website” is not a defined term.

(ii) Proposal To Make Certain Clarifications and Corrections in the Rules

A. Remove Certain Categories Where There Is no Charge

Certain categories are included in the FICC MSBD Schedule of Charges Broker Account Group (“Broker Schedule of Charges”) and the FICC MSBD Schedule of Charges Dealer Account Group (“Dealer Schedule of Charges”) of the MBSD Rules and the FICC MSBD EPN Schedule of Charges in the EPN Rules even though there are no charges associated with those categories.

As such, for simplicity and to enhance clarity, FICC is proposing to remove the category entitled “DK and Modify” from the subsection entitled “Trade Processing” under Section 1 of the Broker Schedule of Charges of the MBSD Rules.

FICC is also proposing to remove the category entitled “DK and Modify” from the subsections entitled (a) “Trade Processing,” (b) “Trade-for-Trade Transactions, Specified Pool Trades, and Stipulated Trades,” and (c) “Option Trades” under Section I of the Dealer Schedule of Charges of the MBSD Rules.

In addition, FICC is also proposing to remove certain categories from the sections entitled “Message Processing Fees” and “Pool Substitution Cancel/Correct” in the FICC MSBD EPN Schedule of Charges. Specifically, FICC proposes to remove the following categories:

- “DK Send or Receive:”
- “Cancel Send or Receive:”
- “Retransmission Request:”
- “Cancel/Correct Receive:”
- “Cancel/Correct DK Send or Receive:”
- “Cancel/Correct Retransmission Request:”

B. Clarify the Rules Related to Notification of Rule Changes

In order to be consistent with similar provisions in the GSD Rules and the EPN Rules and to enhance clarity, FICC is also proposing to add “and Registered Clearing Agencies” to MBSD Rule 27. FICC believes this proposed change would clarify that FICC shall promptly notify Registered Clearing Agencies in addition to Members of any proposal to change, revise, add, or repeal any Rule.

In addition, currently, GSD Rule 36 states that FICC would notify all

Members and registered clearing agencies of any rule change proposals, and MBSD Rule 27 states that FICC would notify all Members of any rule change proposals. Similarly, EPN Article V, Rule 10 states that FICC would notify all EPN Users and registered clearing agencies of any rule change proposals by posting the proposal on the FICC website.

As a clearing agency registered with the Commission, the Act provides a clear framework under which FICC's Rules are adopted and enforced. Under the rule change process, generally, before a proposed rule change may take effect, (i) the change and an explanatory statement must be filed with the Commission and posted by FICC on the FICC website, (ii) notice of the filing and the substantive terms or description of the change must be published by the Commission in the **Federal Register** for public review and comment, and (iii) the Commission must approve the change (or the change must otherwise be permitted to take effect). FICC's Rules are filed with and reviewed by the Commission. As a clearing agency registered under Section 17A of the Act,⁸ a self-regulatory organization subject to Section 19 of the Act,⁹ and a systemically important financial market utility under Title VIII of Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank"),¹⁰ FICC is required to follow: (1) A specified process¹¹ whenever it proposes a new rule or a change or amendment to its Rules and (2) a specified process¹² whenever it proposes to make a change to its rules, procedures or operations that could materially affect the nature or level of risks presented by FICC.

These rule change processes provide notice to Members and provide an opportunity for those parties to comment on such changes. Rule 19b-4 under the Act requires that FICC post any rule change proposals on its website within two business days after the filing of a proposed rule change,¹³ post any rule changes that are approved by the Commission within two business days after it has been notified of the Commission's approval¹⁴ and post any rule change within two business days of

the Commission's notice of such proposed change for rule changes that are effective upon filing.¹⁵ FICC complies—and will continue to comply—with such notice requirements which it believes are adequate.

C. Clarify Certain Provisions Regarding Notice to Interested Persons in the Rules

FICC is proposing to revise certain provisions regarding notice to Interested Persons in GSD Rule 45, MBSD Rule 35 and EPN Article V, Rule 16. Specifically, in the second paragraph of Section 1 of GSD Rule 45, second paragraph of MBSD Rule 35, and EPN Article V, Rule 16, FICC proposes to revise "delivered" to "sufficiently served," so the provision would state that FICC would deem a notice sufficiently served once such notice is posted to the website to be consistent with the other provisions in the first paragraph of Section 1 and Section 2 of GSD Rule 45, the first paragraph of Section 1 and Section 2 of MBSD Rule 35, and the first paragraph of EPN Article V, Rule 16.

FICC would also revise GSD Rule 45, MBSD Rule 35, and EPN Article V, Rule 16 to state that it is the responsibility of the Interested Persons to retrieve notices daily from FICC's website.

FICC would also add a provision to EPN Article V, Rule 16 to state that any notice from an Interested Person to FICC shall be sufficiently served on FICC if the notice is in writing and is delivered, mailed, or transmitted by facsimile machine to FICC at its principal place of business, Attention: Secretary, or such other place as FICC designates in order to be consistent with Section 2 of GSD Rule 45 and Section 2 of MBSD Rule 35. This new provision would also state that any such notice to FICC shall be deemed to have been given when received.

D. Remove Certain Redundant or Unnecessary Provisions for Clarity

FICC is proposing to remove the second paragraph in GSD Rule 2A, Section 3 that states that FICC shall retain the right to deny membership to an applicant if FICC becomes aware of any factor or circumstance about the applicant or its Controlling Management which may impact the suitability of that particular applicant as a Member of FICC because it is redundant.

In addition, FICC proposes to remove "or any Committee thereof" from GSD Rule 47 and MBSD Rule 37 because it is redundant. In addition, FICC proposes to remove "or any committee of the Board," in EPN Article V, Rule 1

because it is also redundant. The definition of "Board of Directors" currently includes committees.

Furthermore, for simplicity and because it is unnecessary, FICC proposes to remove the word "all" before "EPN Users" in EPN Article V, Rule 10.

E. Clarify the Provision Relating to a Special Charge in the GSD Rules

The fourth paragraph in Section 1b(a) of GSD Rule 4 describes a special charge. FICC is proposing to revise the phrase "additional amount" to "additional payment" in this paragraph. To enhance transparency and clarity, FICC would also revise the provision to state that FICC may charge (and not just calculate) an additional payment (a "special charge") applicable to a Margin Portfolio as determined by FICC from time to time in view of market conditions and other financial and operational capabilities of the Member, and FICC would make any such determination based on such factors as FICC determines to be appropriate from time to time. This revised provision would be moved from the fourth paragraph to a new subsection (viii) in Section 1b(a) of GSD Rule 4 preceded by the word "plus."

F. Certain Clarifications and Corrections to GSD Rule 22C

FICC is proposing to make certain clarifications to GSD Rule 22C which describes FICC's interpretation in relation to the Federal Deposit Insurance Corporation Improvement Act of 1991 ("FDICIA").

FICC proposes to correct the title of GSD Rule 22C by adding the word "Improvement" after "Corporation."

FICC would revise "Netting Members" to "Members" in GSD Rule 22C to clarify that the transactions of Members other than Netting Members may be Novated to FICC. Such Members may therefore have net claims against FICC under the GSD Rules, and FICC may have net claims against such Members under the GSD Rules. In each such case, both the Members and FICC intend FDICIA's clearing organization netting provisions to apply.

In addition, FICC is proposing to add "or used" after "defined" in GSD Rule 22C to clarify that some terms discussed in GSD Rule 22C are used in FDICIA but either are not defined at all or not defined in FDICIA.

FICC is also proposing to add "or delivery" in the third and fourth paragraph since the term "payment" as used in FDICIA includes a "noncash

⁸ 15 U.S.C. 78q-1.

⁹ 15 U.S.C. 78s.

¹⁰ 12 U.S.C. 5465(e)(1).

¹¹ This process is set forth in Section 19(b) of the Act and Rule 19b-4 thereunder. 15 U.S.C. 78s(b) and 17 CFR 240.19b-4.

¹² This process is set forth in Section 806(e) of Dodd-Frank and Rule 19b-4 thereunder. 12 U.S.C. 5465(e) and 17 CFR 240.19b-4.

¹³ 17 CFR 240.19b-4(l).

¹⁴ 17 CFR 240.19b-4(m)(2).

¹⁵ *Id.*

payment,”¹⁶ and it is FICC’s and each Member’s intent that both the cash payment and security delivery entitlements and obligations of FICC and each Member be subject to FDICIA’s clearing organization netting provisions.

FICC is also proposing to add “and each Cross-Margining Arrangement and associated agreement and guaranty” in the last paragraph of GSD Rule 22C to clarify the intent of FICC and each Member that the Cross-Margining Arrangements and associated agreements and guaranties are within the scope of Section 404(h) of FDICIA and therefore subject to its protections for “any security agreement or arrangement or other credit enhancement related to one or more netting contracts” between clearing organization members.

FICC would correct references to this Rule 22C. Specifically, FICC would revise references from “this Rule 22C” to “Rule 22B” because Rule 22B (not Rule 22C) provides for the exercise of netting and close-out rights that FICC and its Members intend to be within the scope of FDICIA’s protections.

FICC is also proposing to remove the reference to GSD to reflect the fact that FICC, not GSD, is a “clearing organization” within the meaning of FDICIA.

FICC would also revise the last sentence in GSD Rule 22C to clarify that the netting provided for under Rules 22A and 22B falls within the scope of the general netting protections of Section 404(a) of FDICIA.

G. Other Clarifications and Corrections to the MBSD Rules

To enhance transparency, FICC is proposing to clarify the defined term “Settlement Price” in MBSD Rule 1 to add a case that occurs in current practice. Specifically, FICC proposes to revise subsection (b) to add unallocated TBAs that go through the process for determining the TBA Reprice Transaction Adjustment Payment.

FICC is also proposing correct the defined term “Settlement Value” in MBSD Rule 1 to reflect current practice by (i) removing the references to a Trade-for-Trade Transaction, an SBO-Destined Trade, a Stipulated Trade, and a SBON Trade because only Pool Deliver Obligations, Pool Receive Obligations, and Specified Pool Trades include interest, and (ii) adding a new paragraph for Trade-for-Trade Transactions, an SBO-Destined Trade, a Stipulated Trade, and an SBON Trade that would state that with respect to these types of trades, Settlement Value

would mean the amount in dollars equal to the Par Amount of each Eligible Security that comprises these trades multiplied by the Settlement Price.

FICC is also proposing to add “and SBON Trades” to the definition of “TBA Obligations” and remove “, with respect to” and “settlement obligations generated by the Trade Comparison System” in MSBD Rule 1 to correct an omission and reflect current practice.

FICC would also clarify that the term settlement date in MSBD Rule 8, Section 2B refers to the SIFMA settlement date because the Expanded Pool Netting process only occurs four times a month (during the SIFMA settlement cycle).

In addition, FICC is proposing to add the phrase “for purposes of this Rule 8, hereinafter referred to” before the defined term “ExP Day” in MSBD Rule 8, Section 2B to enhance clarity.

FICC would also add the following cash-only settlement amounts “Miscellaneous Adjustment Amount from TBA Clearing (MIS),”

“Miscellaneous Adjustment Amount from Pool Netting (MSC),” and

“Miscellaneous Adjustment from EPN (MSE)” to MSBD Rule 11, Section 7.

MSBD Rule 11, Section 7 describes the computation of the Cash Balance for each applicable account. Furthermore, FICC would add the defined term “Miscellaneous Adjustment Amount” to MSBD Rule 1, and such definition would be consistent with the definition for the same term in the GSD Rules.

FICC is proposing to add “Date” after “Trade” under Processing Fees of Section I of the Broker Schedule of Charges and under Processing Fees of Section I of the Dealer Schedule of Charges to enhance clarity.

H. Other Clarifications and Corrections to the EPN Rules

To enhance clarity and to be consistent with GSD Rule 44 and MBSD Rule 34, FICC is proposing to revise EPN Article V, Rule 1. Currently, EPN Article V, Rule 1 states that except where action by the Board of Directors, or any committee of the Board, is specifically required by the By-Laws or the EPN Rules, FICC may act by its President, any Managing Director or any Executive Director or by such person, as may be designated from time to time by the Board of Directors. FICC proposes to revise EPN Article V, Rule 1 to state that where action by the Board of Directors is required by the EPN Rules, FICC may act, to the fullest extent permitted by law, by the Chairman of the Board, by its President, any Managing Director or any Executive Director or by such person or persons, whether or not employed by FICC, as may be

designated from time to time by the Board of Directors.

FICC also proposes to correct EPN Article II, Rule 2, Section 3. Specifically, FICC proposes to revise that the Message Summary Report lists the summary totals of each message type by EPN Eligible Security and Participant. This report lists the summary totals of each message type (not list the contents of each message).

FICC also proposes to clarify EPN Article III, Rule 1, Section 2 by removing subsection (a) because FICC does not review an applicant’s financial ability, and FICC does not collect financials for EPN Users.

To enhance clarity, FICC proposes to revise the reference from “Greater than 10 accounts” to “11 Accounts and over” under the section entitled “Account Maintenance Fees” in the FICC MSBD EPN Schedule of Charges.

(iii) Proposal To Make Certain Technical Changes in the Rules

FICC is proposing to make the following technical changes in the Rules to enhance the clarity and readability of the Rules:

A. Grammar-Related Technical Changes

FICC is proposing to make certain grammar-related technical changes. FICC is proposing to make a conforming grammatical change in the final paragraph of GSD Rule 22C to change “relating” to “related.” FICC is also proposing to revise “payments” to “payment” as a conforming grammatical change in GSD Rule 22C. FICC would also remove the word “which” in GSD Rule 11B, Section (a) to make a grammatical correction. FICC would add the word “or” as a grammatical correction in the definition of “Settlement Value” in MSBD Rule 1. FICC is also proposing to make a conforming grammatical change to remove the comma in the definition of “TBA Obligations” in MBSD Rule 1.

B. Correct Typographical Errors

FICC is proposing to revise “An” to “Any” to correct a typographical error in the fourth paragraph of GSD Rule 22C.

C. Other Technical Changes

FICC is also proposing to make the technical changes described below.

- conform the use of dashes in Section 2 of GSD Rule 38 and Section 2 of MBSD Rule 29.
- revise the comma to a semi-colon in the last paragraph of GSD Rule 22C.
- add a comma in the last sentence of GSD Rule 22C, in the defined term “Clearing System” in MBSD Rule 1.

¹⁶ See 12 U.S.C. 4402(15).

- add a hyphen between “the” and “Market” in the defined term “Off-the-Market Transaction” in MBSD Rule 1.
- correct a section reference in MSBD Rule 11, Section 7(l) by revising the reference from Section 6 to Section 10.
- make conforming changes to MBSD Rule 11, Section 7 to replace the comma with a semi-colon and add plus or minus after the items described in subsections (o), (p), and (q).
- make a conforming change to EPN Article III, Rule 1, Section 2 by revising subsections (b) and (c) to subsections (a) and (b), respectively because FICC is proposing to remove subsection (a), as described above.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.¹⁷

The proposed changes to (i) correct or clarify the use of certain defined terms in the Rules, (ii) make certain clarifications and corrections in the Rules, and (iii) make certain technical changes to the Rules would help to ensure that the Rules are accurate and clear to participants. When participants better understand their rights and obligations regarding the Rules, such participants are more likely to act in accordance with the Rules, which FICC believes would promote the prompt and accurate clearance and settlement of securities transactions. As such, FICC believes that the proposed changes would be consistent with Section 17A(b)(3)(F) of the Act.¹⁸

(B) Clearing Agency’s Statement on Burden on Competition

FICC does not believe the proposed rule changes to (i) correct or clarify the use of certain defined terms in the Rules, (ii) make certain clarifications and corrections in the Rules, and (iii) make certain technical changes to the Rules would impact competition. The proposed rule changes would help to ensure that the Rules remain clear and accurate. In addition, the changes would facilitate participants’ understanding of the Rules and their obligations thereunder. These changes would not affect FICC’s operations or the rights and obligations of the membership. As such, FICC believes the proposed rule changes would not have any impact on competition.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

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)¹⁹ of the Act and paragraph (f)²⁰ of Rule 19b–4 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 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–FICC–2021–005 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2021–005. 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 FICC and on DTCC’s website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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–FICC–2021–005 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–14802 Filed 7–12–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92333; File No. SR–NYSEArca–2021–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the First Trust SkyBridge Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E

July 7, 2021.

On May 6, 2021, NYSE Arca, Inc. (“NYSE Arca”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b–4 thereunder,² a proposed rule change to list and trade shares of the First Trust SkyBridge Bitcoin ETF Trust under NYSE Arca Rule 8.201–E. The proposed rule change was published for comment in the **Federal Register** on May 27, 2021.³ The Commission has received

²¹ 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. 91962 (May 21, 2021), 86 FR 28646 (May 27, 2021).

¹⁷ 15 U.S.C. 78q–1(b)(3)(F).

¹⁸ *Id.*

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b–4(f).

comments on the proposed rule change.⁴

Section 19(b)(2) of the Act⁵ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 11, 2021. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the comments received. Accordingly, pursuant to Section 19(b)(2) of the Act,⁶ the Commission designates August 25, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-NYSEArca-2021-37).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-14790 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92336; File No. SR-NYSEAMER-2021-32]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 903 To Limit Short Term Options Series Intervals

July 7, 2021.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b-4 thereunder,³

⁴ Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nysearca-2021-37/srnysearca202137.htm>.

⁵ 15 U.S.C. 78s(b)(2).

⁶ *Id.*

⁷ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

notice is hereby given that on June 25, 2021, NYSE American LLC (“NYSE American” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 903 (Series of Options Open for Trading) in connection with limiting the number of strikes listed for Short Term Option Series which are available for quoting and trading on the Exchange. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 903 (Series of Options Open for Trading). Specifically, this proposal seeks to widen the intervals between strikes in order to limit the number of strikes listed for multiply listed equity options classes (excluding options on Exchange-Traded Funds (“ETFs”) and Section 107 Securities (as described herein, *see infra* n. 13) within the Short Term Option Series program that have an expiration date more than 21 days from the listing date.

Background

Current Rule 903 permits the Exchange, after a particular class of options has been approved for listing and trading on the Exchange, to open for

trading series of options therein. The Exchange may list series of options for trading on a weekly,⁴ monthly⁵ or quarterly⁶ basis. Rule 903 (c) sets forth the intervals between strike prices of series of options on individual stocks generally⁷ and Rule 903 Commentary .10 (d) specifically sets forth intervals between strike prices Short Term Option Series. Additionally, the Exchange may list series of options pursuant to the \$1 Strike Price Interval Program,⁸ the \$0.50 Strike Program,⁹ the \$2.50 Strike Price Program,¹⁰ and the \$5 Strike Program.¹¹ The Exchange’s proposal seeks to amend the listing of weekly series of options (*i.e.* Short Term Option Series) by adopting new Rule 903 Commentary .10 (e),¹² which widens the permissible intervals between strikes, thereby limiting the number of strikes listed, for multiply listed equity options (excluding options

⁴ The weekly listing program is known as the Short Term Option Series Program and is described within Rule 903, Commentary .10.

⁵ The Exchange will open at least one expiration month for each class of options open for trading on the Exchange. *See* Rule 903(a). The monthly expirations are subject to certain listing criteria for underlying securities described within Rule 915. Monthly listings expire the third Friday of the month *See* The Options Clearing Corporation (“OCC”) By-Laws at Section 1.

⁶ The quarterly listing program is known as the Quarterly Options Series Program and is described within Rule 903.

⁷ The interval between strike prices of series of options on individual stocks may be \$2.50 or greater where the strike price is \$25 or less, provided however, that the Exchange may not list \$2.50 intervals below \$50 (*e.g.* \$12.50, \$17.50) for any class included within the \$1 Strike Price Program, as detailed below in Rule 903 Commentary .06 if the addition of \$2.50 intervals would cause the class to have strike price intervals that are \$0.50 apart. For series of options on Exchange-Traded Fund Shares that satisfy the criteria set forth in Rule 915 Commentary .06, the interval of strike prices may be \$1 or greater where the strike price is \$200 or less or \$5 or greater where the strike price is over \$200. Exceptions to the strike price intervals above are set forth in Rule 903, Commentary .07.

⁸ The \$1 Strike Interval Program is described within Rule 903, Commentary .06

⁹ The \$0.50 Strike Program is described within Rule 903, Commentary .13

¹⁰ The \$2.50 Strike Price Program is described within Rule 903, Commentary .07

¹¹ The \$5 Strike Program is described within Rule 903, Commentary .12

¹² As a result, the proposed rule change subsequently updates current Rule 903, Commentary .10(e) to (f). In this regard, the Exchange also proposes to update a cross-reference to this newly re-lettered paragraph .10(g) that appears in Rule 903(h). *See* proposed Rule 903(h).

on ETFs¹³ and Section 107 Securities¹⁴)

¹³ The term “ETF” (Exchange-Traded Fund) (or “Fund Shares”) has the same meaning as the term “exchange-traded fund” as defined in Rule 6c–11 under the Investment Company Act of 1940. See Rule 915, Commentary .06(g). Securities deemed appropriate for options trading shall include shares or other securities (“Fund Shares”), including but not limited to Partnership Units as defined in this Rule, that are principally traded on a national securities exchange and are defined as an “NMS stock” under Rule 600 of Regulation NMS, and that (1) represent interests in registered investment companies (or series thereof) organized as open-end management investment companies, unit investment trusts or similar entities, and that hold portfolios of securities comprising or otherwise based on or representing investments in indexes or portfolios of securities (or that hold securities in one or more other registered investment companies that themselves hold such portfolios of securities) (“Funds”) and/or financial instruments including, but not limited to, stock index futures contracts, options on futures, options on securities and indexes, equity caps, collars and floors, swap agreements, forward contracts, repurchase agreements and reverse repurchase agreements (the “Financial Instruments”), and money market instruments, including, but not limited to, U.S. government securities and repurchase agreements (the “Money Market Instruments”) constituting or otherwise based on or representing an investment in an index or portfolio of securities and/or Financial Instruments and Money Market Instruments, or (2) represent commodity pool interests principally engaged, directly or indirectly, in holding and/or managing portfolios or baskets of securities, commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or non-U.S. currency (“Commodity Pool ETFs”) or (3) represent interests in a trust or similar entity that holds a specified non-U.S. currency or currencies deposited with the trust or similar entity when aggregated in some specified minimum number may be surrendered to the trust by the beneficial owner to receive the specified non-U.S. currency or currencies and pays the beneficial owner interest and other distributions on the deposited non-U.S. currency or currencies, if any, declared and paid by the trust (“Currency Trust Shares”), or (4) represent interests in the SPDR Gold Trust or are issued by the iShares COMEX Gold Trust or iShares Silver Trust).

¹⁴ Securities deemed appropriate for options trading shall include shares or other securities (“Index-Linked Securities”, “Commodity-Linked Securities”, “Currency-Linked Securities”, “Fixed Income-Linked Securities”, “Futures-Linked Securities”, and “Combination-Linked Securities”, collectively known as “Section 107 Securities”), as defined in Sections 107D, 107E, 107F, 107G, 107H and 107I of the Company Guide, that are principally traded on a national securities exchange and an “NMS stock” (as defined in Rule 600 of Regulation NMS under the Securities and Exchange Act of 1934), and represent ownership of a security that provides for the payment at maturity, as described below: Index-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of an underlying index or indexes of equity securities (“Equity Reference Asset”); Commodity-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of one or more physical commodities or commodity futures, options on commodities, or other commodity derivatives or Commodity-Based Trust Shares or a basket or index of any of the foregoing (“Commodity Reference Asset”); Currency-Linked Securities are securities that provide for the payment at maturity of a cash

that have an expiration date more than 21 days from the listing date. This proposal does not amend the monthly or quarterly listing rules, nor does it amend the \$1 Strike Price Interval Program, the \$0.50 Strike Program, the \$2.50 Strike Price Program, or the \$5 Strike Program.

Short Term Option Series Program

After an option class has been approved for listing and trading on the Exchange,¹⁵ Rule 903(h) permits the

amount based on the performance or the leveraged (multiple or inverse) performance of one or more currencies, or options on currencies or currency futures or other currency derivatives or Currency Trust Shares (as defined in Rule 1200B—AEMI(b)) or a basket or index of any of the foregoing (“Currency Reference Asset”); Fixed Income-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of one or more notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities (“Treasury Securities”), government-sponsored entity securities (“GSE Securities”), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof or a basket or index of any of the foregoing (“Fixed Income Reference Asset”); Futures-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of an index or indexes of futures contracts or options or derivatives on futures contracts (a “Futures Reference Asset”); and Combination-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of any combination of two or more Equity Reference Assets, Commodity Reference Assets, Currency Reference Assets, Fixed Income Reference Assets, or Futures Reference Assets (a “Combination Reference Asset”).

¹⁵ The Exchange may have no more than a total of five Short Term Option Expiration Dates, not including any Monday or Wednesday SPY Expirations as provided in paragraph (g). If the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on the Friday that the options are set to expire, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday. See Rule 903, Commentary .10. The Exchange may open for trading on any Friday or Monday that is a business day series of options on the SPDR S&P 500 ETF Trust (“SPY”) to expire on any Monday of the month that is a business day and is not a Monday on which Quarterly Options Series expire (“Monday SPY Expirations”), provided that any Friday on which the Exchange opens for trading a Monday SPY Expiration is one business week and one business day prior to expiration. The Exchange may also open for trading on any Tuesday or Wednesday that is a business day series of SPY options to expire on any Wednesday of the month that is a business day and is not a Wednesday on which Quarterly Options Series expire (“Wednesday SPY Expirations”). The Exchange may list up to five consecutive Monday SPY Expirations and up to five consecutive Wednesday SPY Expirations at one time; the Exchange may have no more than a total of five Monday SPY Expirations and no more than a total of five Wednesday SPY Expirations. Monday and

Exchange to open for trading on any Thursday or Friday that is a business day (“Short Term Option Opening Date”) series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays on which monthly options series or Quarterly Options Series expire (“Short Term Option Expiration Dates”). The Exchange may select up to fifty currently listed option classes on which Short Term Option Series may be opened on any Short Term Option Opening Date. In addition to the fifty option class restriction, the Exchange may also list Short Term Option Series on any option classes that are selected by other securities exchanges that employ a similar program under their respective rules. For each option class eligible for participation in the Short Term Option Series Program, the Exchange may open up to 30 Short Term Option Series for each expiration date in that class. The Exchange may also open Short Term Option Series that are opened by other securities exchanges in option classes selected by such exchanges under their respective short term option rules.¹⁶ Pursuant to Rule 903, Commentary .10 (b), the Exchange may open up to 30 initial series for each option class that participates in the Short Term Option Series Program and, pursuant to Rule 903, Commentary .10 (c), if the Exchange opens less than 30 Short Term Option Series for a Short Term Option Expiration Date, additional series may be opened for trading on the Exchange when Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. Rule 903, Commentary .10 (d) provides that, if the class does not trade in \$1 strike price intervals, the strike price interval for Short Term Option Series may be: (i) \$0.50 or greater where the strike price is less than \$75; (ii) \$1.00 or greater where the strike price is between \$75 and \$150; or (iii) \$2.50 or greater for strike prices greater than \$150.¹⁷

Wednesday SPY Expirations will be subject to the provisions of this Rule. See Rule 903, Commentary .10(e). With the exception of Monday and Wednesday SPY Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire or, in the case of Quarterly Options Series, on an expiration that coincides with an expiration of Quarterly Options Series on the same class. See Rule 903, Commentary .10(e).

¹⁶ See Rule 903, Commentary .10(a).

¹⁷ Additionally, Rule 903, Commentary .10 (d) provides that the interval between strike prices on Short Term Option Series shall be the same as the

The Exchange notes that listings in the weekly program comprise a significant part of the standard listing in options markets and that the industry has observed a notable increase over approximately the last five years in compound annual growth rate (“CAGR”) of weekly strikes as compared to CAGR for standard third-Friday expirations.¹⁸

Proposal

The Exchange proposes to widen the intervals between strikes in order to limit the number of strikes listed for equity options (excluding options on ETFs and Section 107 Securities) listed as part of the Short Term Option Series Program that have an expiration date more than 21 days from the listing date,

by adopting proposed Rule 903, Commentary .10 (e). The Exchange notes that this proposal is substantively identical to the strike interval proposal recently submitted by Nasdaq BX, Inc. (“BX”) and approved by the Securities and Exchange Commission (“Commission”).¹⁹

The proposal widens intervals between strikes for expiration dates of equity option series (excluding options on ETFs and Section 107 Securities) beyond 21 days utilizing the three-tiered table in proposed Rule 903, Commentary .10 (e) (presented below) which considers both the Share Price and Average Daily Volume for the option series. The table indicates the applicable strike intervals and

supersedes Rule 903, Commentary .10 (c), which currently permits 10 additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. As a result of the proposal Rule 903, Commentary .10(e) would not permit an additional series of an equity option to have an expiration date more than 21 days from the listing date to be opened for trading on the Exchange despite the noted circumstances in paragraph (c) when such additional series may otherwise be added.

Tier	Average daily volume	Share price				
		Less than \$25	\$25 to less than \$75	\$75 to less than \$150	\$150 to less than \$500	\$500 or greater
1	Greater than 5,000	\$0.50	\$1.00	\$1.00	\$5.00	\$5.00
2	Greater than 1,000 to 5,000	1.00	1.00	1.00	5.00	10.00
3	0 to 1,000	2.50	5.00	5.00	5.00	10.00

Proposed 903, Commentary .10 (e)(1) provides that the Share Price is the closing price on the primary market on the last day of the calendar quarter. This value is used to derive the column from which to apply strike intervals throughout the next calendar quarter. Also, proposed Rule 903, Commentary .10 (e)(1) provides that in the event of a corporate action, the Share Price of the surviving company is utilized.²⁰ Proposed Rule 903, Commentary .10 (e)(2) provides that the Average Daily Volume is the total number of option contracts traded in a given security for the applicable calendar quarter divided by the number of trading days in the applicable calendar quarter. Beginning on the second trading day in the first month of each calendar quarter, the Average Daily Volume is calculated by utilizing data from the prior calendar quarter based on Customer-cleared volume at OCC. For options listed on the first trading day of a given calendar

quarter, the Average Daily Volume is calculated using the calendar quarter prior to the last trading calendar quarter.²¹ Pursuant to current Rule 903, Commentary .10, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday.

By way of example, if the Share Price for a symbol was \$142 at the end of a calendar quarter, with an Average Daily Volume greater than 5,000, thereby, requiring strike intervals to be listed \$1.00 apart, that strike interval would apply for the calendar quarter, regardless of whether the Share Price changed to \$150 or greater during that calendar quarter.²² The proposed table within Rule 903, Commentary .10(e) takes into account the notional value of a security, as well as Average Daily Volume in the underlying stock, in order to widen the intervals between

strikes and thereby limit the number of strikes listed for equity options (excluding options on ETFs and Section 107 Securities) in the Short Term Option Series listing program. The Exchange will utilize OCC Customer-cleared volume, as customer volume is an appropriate proxy for demand. The OCC Customer-cleared volume represents the majority of options volume executed on the Exchange, which, in turn, reflects the demand in the marketplace. The options series listed on the Exchange are intended to meet customer demand by offering an appropriate number of strikes. Non-Customer cleared OCC volume generally represents the supply side.

The proposal is intended to remove repetitive and unnecessary strike listings across the weekly expiries. Specifically, the proposal seeks to reduce the number of strikes listed in the furthest weeklies, which generally have wider markets and therefore lower

strike prices for series in that same option class that expire in accordance with the normal monthly expiration cycle. During the expiration week of an option class that is selected for the Short Term Option Series Program pursuant to this rule (“Short Term Option”), the strike price intervals for the related non-Short Term Option (“Related non-Short Term Option”) shall be the same as the strike price intervals for the Short Term Option.

¹⁸ See Securities Exchange Act Release No. 91125 (February 12, 2021), 86 FR 10375 (February 19, 2021) (SR-BX-2020-032) (“BX Strike Interval Approval Order”); and SR-2020-BX-032 as amended by Amendment No. 1 (February 10, 2021) available at: <https://www.sec.gov/comments/sr-bx-2020-032/srbx2020032-8359799-229182.pdf> (“BX proposal”); see also BX Options Strike Proliferation Proposal (February 25, 2021) available at: <https://www.nasdaq.com/solutions/bx-options-strike-proliferation-proposal>.

¹⁹ See BX Strike Interval Approval Order, *id.*

²⁰ The Exchange notes that corporate actions resulting in change ownership would result in a surviving company, such as a merger of two publicly listed companies, and the Share Price of the surviving company would be used to determine strike intervals pursuant to the proposed table. Corporate actions that do not result in a change of ownership, such as stock-splits or distribution of

special cash dividends, would not result in a “surviving company,” therefore would not impact which Share Price to apply pursuant to the proposed Rule.

²¹ For example, options listed as of April 1, 2021 would be calculated on April 2, 2021 using the Average Daily Volume from October 1, 2020 to December 31, 2020.

²² The Exchange notes that any strike intervals imposed by the Exchange's Rules will continue to apply. In this example, the strikes would be in \$1 intervals up to (but not including) \$150, which is the upper limit imposed by Rule 903, Commentary .10(d).

market quality.²³ The proposed strike intervals are intended to widen permissible strike intervals in multiply listed equity options (excluding options on ETFs and Section 107 Securities) where there is less volume as measured by the Average Daily Volume tiers. Therefore, the lower the Average Daily Volume, the greater the proposed spread between strike intervals. Options classes with higher volume contain the most liquid symbols and strikes, which the Exchange believes makes the finer proposed spread between strike intervals for those symbols appropriate. Additionally, lower-priced shares have finer strike intervals than higher-priced shares when comparing the proposed spread between strike intervals. Today, weeklies are available on 16% of underlying products. The proposal limits the density of strikes listed in series of options, without reducing the classes of options available for trading on the Exchange. Short Term Option Series with an expiration date greater than 21 days from the listing date currently equate to 7.5% of the total number of strikes in the options market, which equals 81,000 strikes.²⁴ The Exchange expects this proposal to result in the limitation of approximately 20,000 strikes within the Short Term Option Series, which is approximately 2% of the total strikes in the options markets.²⁵ The Exchange understands there has been an inconsistency of demand for series of options beyond 21 calendar days.²⁶ The proposal takes into account customer demand for certain options classes, by considering both the Share Price and the Average Daily Volume, in order to remove certain strike intervals where there exist clusters of strikes whose characteristics closely resemble one another and, therefore, do not serve different trading

needs,²⁷ rendering these strikes less useful. The Exchange also notes that the proposal focuses on strikes in multiply listed equity options, and excludes ETFs and Section 107 Securities, as the majority of strikes reside within equity options.

Additionally, proposed Rule 903, Commentary .07(e)(3) provides that options that are newly eligible for listing pursuant to Rule 915 and designated to participate in the Short Term Option Series program pursuant to Rule 903, Commentary .10(e) will not be subject to subparagraph (e) (as proposed) until after the end of the first full calendar quarter following the date the option class was first listed for trading on any options market.²⁸ As proposed, the Exchange is permitted to list options on newly eligible listings, without having to apply the wider strike intervals, until the end of the first full calendar quarter after such options were listed. The proposal thereby permits the Exchange to add strikes to meet customer demand in a newly listed options class. A newly eligible option class may fluctuate in price after its initial listing; such volatility reflects a natural uncertainty about the security. By deferring the application of the proposed wider strike intervals until after the end of the first full calendar quarter, additional information on the underlying security will be available to market participants and public investors, as the price of the underlying has an opportunity to settle based on the price discovery that has occurred in the primary market during this deferment period. Also, the Exchange has the ability to list as many strikes as are permissible for the Short Term Option Series once the expiry is no more than 21 days. Short Term Option Series that have an expiration date no more than 21 days from the listing date are not subject to the proposed strike intervals, which allows the Exchange to list additional, and potentially narrower, strikes in the event of market volatility or other market events. These metrics are intended to align expectations for determining which strike intervals will be utilized. Finally, proposed Rule 903, Commentary .10(e)(4) provides that, notwithstanding the strike intervals imposed in proposed subparagraph (e),

the proposal does not amend the range of strikes that may be listed pursuant to subparagraph (d).

While the current listing rules permit the Exchange to list a number of weekly strikes on its market, in an effort to encourage Market Makers to deploy capital more efficiently, as well as improve displayed market quality, the proposal aims to reduce the density of strikes listed in later weeks by widening the intervals between strikes listed for equity options (excluding options on ETFs and Section 107 Securities) which have an expiration date more than 21 days from the listing date. The Exchange requires Specialists and e-Specialists ("Specialists") and Market Makers to quote during a certain amount of time in the trading day and in a certain percentage of series in their assigned options classes to maintain liquidity in the market.²⁹ With an increasing number of strikes being listed across options exchanges, Market Makers must expend their capital to ensure that they have the appropriate infrastructure to meet their quoting obligations on all options markets in which they are assigned in option classes. The Exchange believes that by widening the intervals between strikes listed for equity options (excluding options on ETFs and Section 107 Securities), thus reducing the number of strikes listed on the Exchange, the proposal will likewise reduce the number of weekly strikes in which Specialists and Market Makers are required to quote and, as a result, allow Specialists and Market Makers to expend their capital in the options market in a more efficient manner. Due to this increased efficiency, the Exchange believes that the proposal may improve overall market quality on the Exchange by widening the intervals between strikes in multiply listed equity options (excluding options on ETFs and Section 107 Securities) that have an expiration date more than 21 days from the listing date. The proposal is intended to balance the goal of limiting the number of listed strikes with the needs of market participants. The Exchange believes that the various permissible strike intervals will continue to offer market participants the ability to select the appropriate strikes to meet their investment objectives.

Implementation

The Exchange will announce the implementation date of the proposed rule change by Trader Update to be published no later than 30 days following the operative date of the proposed rule. The implementation date

²³ See BX proposal, *supra* note 18, which presents tables that focus on data for 10 of the most and least actively traded symbols and demonstrate average spreads in weekly options during the month of August 2020.

²⁴ The Exchange notes that this proposal is an initial attempt at reducing strikes and anticipates filing additional proposals to continue reducing strikes. The percentage of underlying products and percentage of and total number of strikes, are approximations and may vary slightly at the time of this filing. The Exchange intends to decrease the overall number of strikes listed on the NYSE Group options exchanges in a methodical fashion, so that it may monitor progress and feedback from its ATP Holders. The Exchange also notes that its affiliated options exchange, NYSE Arca Options, Inc. plans to submit an identical proposal.

²⁵ From information drawn from time period between January 2020 and May 2020. See BX proposal, *supra* note 18.

²⁶ See BX proposal, *supra* note 18.

²⁷ For example, two strikes that are densely clustered may have the same risk properties and may also be the same percentage out-of-the money.

²⁸ For example, if an options class became newly eligible for listing pursuant to Rule 5.3—O on March 1, 2021 (and was actually listed for trading that day), the first full quarterly lookback would be available on July 1, 2021. This option would become subject to the proposed strike intervals on July 2, 2021.

²⁹ See Rule 925.1NY.

will be no later than 30 days following the issuance of the Trader Update. The Exchange will issue a Trader Update³⁰ to its ATP Holders whenever the Exchange is the first exchange to list a class as eligible for Short Term Option Series pursuant to Rule 903, Commentary .10(e).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.³¹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³² requirements that the rules of an 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, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposal seeks to widen the permissible intervals between strikes listed for equity options (excluding options on ETFs and Section 107 Securities) in order to limit the number of strikes listed in the Short Term Option Series program that have an expiration date more than 21 days. The proposal removes impediments to and perfects the mechanism of a free and open market and a national market system by encouraging Market Makers to deploy capital more efficiently, which may improve market quality overall on the Exchange, by widening the intervals between strikes when applying the strike interval table to

multiply listed equity options (excluding options on ETFs and Section 107 Securities) that have an expiration date more than 21 days from the listing date. As described above, the Exchange requires Specialists and Market Makers to quote during a certain amount of time in the trading day and in a certain percentage of series in their assigned options classes to maintain liquidity in the market.³⁴ With an increasing number of strikes due, in part, to tighter intervals being listed across options exchanges, Market Makers must expend their capital to ensure that they have the appropriate infrastructure to meet their quoting obligations on all options markets in which they are assigned in options classes. The Exchange believes that this proposal will widen the intervals between strikes listed on the Exchange, thereby reducing the number of weekly options listed on its market in later weeks in which Market Makers are required to quote and, in turn, allowing DPMs and Market Makers to expend their capital in the options market in a more efficient manner.

The Exchange believes that limiting the permissible strikes for multiply listed equity options (excluding options on ETFs and Section 107 Securities) that have an expiration date more than 21 days from the listing date will not significantly disrupt the market, as the majority of the volume traded in weekly options exists in options series which have an expiration date of 21 days or less. The proposal will limit the number of strikes listed in series of options without reducing the number of classes of options available for trading on the Exchange. The proposal allows the Exchange to determine the weekly strike intervals for multiply listed equity Short Term Option Series listed in the later weeks by taking into account customer demand for certain options classes by considering both the Share Price and the Average Daily Volume in the underlying security. The Exchange utilizes OCC Customer-cleared volume, as customer volume is an appropriate proxy for demand. Whereas non-Customer cleared OCC volume generally represents the supply side, the Exchange believes OCC Customer-cleared volume represents the majority of options volume executed on the Exchange, which, in turn, reflects the demands in the marketplace and is therefore intended to assist the Exchange in meeting customer demand by offering an appropriate number of strikes.

The proposal is intended to remove certain strikes where there exist clusters of strikes whose characteristics closely

resemble one another and, therefore, do not serve different trading needs, which currently results in less useful strikes. As such, the proposal protects investors and the general public by removing unnecessary choices for an options series, which the Exchange believes may improve market quality. The proposal seeks to reduce the number of strikes in the furthest weeklies, which generally have wider markets, and, therefore, lower market quality. The implementation of the Strike Interval table is intended to allow for greater spreads between strike intervals in multiply listed equity options where there is less volume as measured by the Average Daily Volume tiers. Therefore, the lower the Average Daily Volume, the wider the proposed spread between strike intervals, and the higher the Average Daily Volume (*i.e.*, the options classes that contain the most liquid symbols and strikes), the narrower the proposed spread between strike intervals. Additionally, the proposed strike intervals are finer for lower-priced shares than higher-priced shares.³⁵ As a result, the Exchange believes that, by limiting the permissible strikes for multiply listed equity options (excluding options on ETFs and Section 107 Securities) that have an expiration date more than 21 days from the listing date pursuant to the proposed Strike Interval table, the proposal may improve overall market quality on the Exchange, which serves to protect investors and the general public.

Further, utilizing the second trading day of a calendar quarter allows the Exchange to accumulate data regarding OCC Customer-cleared volume from the entire prior calendar quarter and allows the calculation of Average Daily Volume to account for trades executed on the last day of the previous calendar quarter, which will have settled by the second trading day.³⁶ The Exchange believes that applying the previous calendar quarter for the calculation is appropriate to reduce the impact of unusual trading activity as a result of unique market events, such as a corporate action (*i.e.*, it may result in a more reliable measure of Average Daily Volume than a shorter period).

As stated, the proposal is substantively identical to the strike interval proposal recently submitted by BX and approved by the Commission.³⁷

³⁰ When the Exchange is the first exchange to list an option class Rule 6.4–O, Commentary .07 the Exchange shall provide a Trader Notice OTP Holders regarding the Short Term Option Series to be listed. Such notice will include for each eligible option class: the closing price of the underlying, the Average Daily Volume of the option class; and the eligible strike category (per the proposed table) in which the eligible option class falls under as a result of the closing price and the Average Daily Volume.

³¹ 15 U.S.C. 78f(b).

³² 15 U.S.C. 78f(b)(5).

³³ *Id.*

³⁴ See *supra* note 30.

³⁵ The Exchange notes that it has discussed the proposed strike intervals with various ATP Holders.

³⁶ Options contracts settle one business day after trade date. Strike listing determinations are made the day prior to the start of trading in each series.

³⁷ See BX Strike Interval Approval Order, *supra* note 18.

The Exchange believes that varied strike intervals will continue to offer market participants the ability to select the appropriate strike interval to meet that market participants' investment objectives.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as the proposed rule change limits the number of Short Term Option Series strikes available for quoting and trading on the Exchange for all market participants. Therefore, all market participants will equally be able to transact in options series in the strikes listed for trading on the Exchange. The proposal is intended to reduce the number of strikes for weekly options listed in later weeks without reducing the number of classes of options available for trading on the Exchange while also continuing to offer an appropriate number of strikes the Exchange believes will meet market participants' investment objectives.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as it only impacts the permissible strike intervals for certain options series listed on the Exchange. Additionally, another options exchange has recently implemented a substantively identical rule for listing Short Term Option Series strike intervals on its exchange, approved by the Commission.³⁸ The proposal is a competitive response that will permit the Exchange to list the same series in multiply listed options as another options exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii)³⁹ of the Act and Rule 19b-4(f)(6) thereunder.⁴⁰ Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act and subparagraph (f)(6) of Rule 19b-4 thereunder.⁴¹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act⁴² normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)⁴³ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may implement the proposed rule change at the same time that all other options exchanges implement their respective rule changes. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change is substantively identical to rules adopted by each other options exchange, and therefore the Exchange's proposal does not raise any new or novel issues. Waiver of the operative delay will allow the Exchange to implement its new rule on the same timeline as the other options exchanges, and such coordinated implementation will reduce potential investor confusion and facilitate a harmonized approach to strike listings for options within the Short Term Option Series program that have an expiration date more than 21 days from the listing date. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.⁴⁴

³⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴⁰ 17 CFR 240.19b-4(f)(6).

⁴¹ In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁴² 17 CFR 240.19b-4(f)(6).

⁴³ 17 CFR 240.19b-4(f)(6)(iii).

⁴⁴ For purposes only of waiving the 30-day operative delay, the Commission also has

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEAMER-2021-32 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-NYSEAMER-2021-32. 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

considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³⁸ See BX Strike Interval Approval Order, *supra* note 18.

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–NYSEAMER–2021–32, and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁵

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–14793 Filed 7–12–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92342; File No. SR–DTC–2021–011]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Proposed Rule Change Relating to Confidential Information, Market Disruption Events, and Other Changes

July 7, 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 June 25, 2021, The Depository Trust Company (“DTC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. 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 proposed rule change consists of modifications to DTC’s Rules, Bylaws and Organization Certificate (the “Rules”)³ to (i) revise certain provisions in the Rules relating to the confidentiality of information furnished by Participants⁴ to DTC, (ii) require that

each Participant maintain confidential information furnished by DTC or its affiliates in confidence, and restrict use and disclosure of such information, (iii) add certain officers who are allowed to determine that there is a Market Disruption Event pursuant to Rule 38 and (iv) add a new Rule 38(A) to address situations in which it is necessary to disconnect a Participant, or third party service provider, or service bureau due to an imminent threat of harm to DTC, Participants and/or other market participants. Each of the proposed changes is described in greater detail below.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency 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

1. Purpose

The proposed rule change consists of modifications to (i) revise certain provisions in the Rules relating to the confidentiality of information furnished by Participants to DTC, (ii) require that each Participant maintain confidential information furnished by DTC or its affiliates in confidence and restrict use and disclosure of such information, (iii) add certain officers who are allowed to determine that there is a Market Disruption Event pursuant to Rule 38 and (iv) add a new Rule 38(A) to address situations in which it is necessary to disconnect a Participant, or third party service provider, or service bureau due to an imminent threat of harm to DTC, Participants and/or other market participants. Each of the proposed changes is described in greater detail below.

(i) DTC Confidentiality Requirements

Section 1 of Rule 2⁵ contains provisions relating to confidentiality of

the context otherwise requires or (ii) the Procedures otherwise provide. Section 1 of Rule 2, *id.*

⁵ Rule 2 relates to initial and ongoing requirements to become and continue to be a Participant and/or Pledgee, including information that DTC may require applicants or Participants to provide to DTC. *Id.*

information furnished by Participants to DTC (collectively, the “DTC Confidentiality Requirements”). Each of the DTC Confidentiality Requirements provides that the rights of DTC to inspect books and records, or to be furnished with information, is subject to any applicable laws or rules, or regulations of regulatory bodies having jurisdiction over the Participant, that relate to confidentiality of records. DTC is proposing to update the DTC Confidentiality Requirements because such provisions (i) may result in unequal treatment of Participants due to differing laws or regulations of regulatory bodies, (ii) may result in a potential conflict of laws where rules or regulations governing a regulatory body of a Participant differ from the laws applicable to DTC, or a Participant has multiple regulatory bodies whose rules conflict, (iii) are burdensome as they require DTC to track the rules and regulations of each regulatory body of its Participants to determine what applicable laws or rules or regulations of regulatory bodies that relate to confidentiality of records affect its rights to receive information and (iv) are unnecessary as DTC has sufficient protections in place relating to protection and confidentiality of Participant data.

The regulatory bodies that have jurisdiction over Participants differ by Participant depending on certain criteria of each Participant, including the type of entity of the Participant, where the Participant was organized, the types of businesses in which the Participant engages and where the Participant is doing business. In addition, many Participants are regulated by more than one regulatory body. As a result, a requirement to maintain confidentiality standards for information provided by a Participant or the right to receive information based on the regulatory body or bodies that regulate such Participant result in varying standards of confidentiality for Participants that are regulated by different regulatory bodies. Such varying standards may result in unequal treatment of Participants due to differing laws or regulations of the regulatory body or bodies governing such Participants. In addition, such varying standards may result in a potential conflict of laws where rules or regulations governing a regulatory body of a Participant differ from the laws applicable to DTC or an entity that has multiple regulatory bodies whose rules conflict.

DTC believes that it is unnecessarily burdensome to determine the rules and regulations of each of the regulatory bodies that regulate its Participants.

⁴⁵ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ Capitalized terms not defined herein are defined in the Rules, available at <https://www.dtcc.com/legal/rules-and-procedures>.

⁴ As provided in the Rules, the term “Participant” includes the term “Limited Participant” unless (i)

Such regulatory bodies include numerous U.S. federal and state regulators as well as foreign national, state and local regulators. DTC proposes revising the language in the DTC Confidentiality Requirements to maintain one confidentiality standard for all Participants rather than maintaining potentially different confidentiality standards for Participants based on the various, unrelated regulatory bodies regulating such Participants. DTC is proposing to replace the existing language in the DTC Confidentiality Requirements with language that would provide that DTC will hold non-public information furnished pursuant to those Rules in confidence as may be required under the law or the rules and regulations applicable to DTC that relate to the confidentiality of records. Such laws, rules and regulations would include national, state and foreign laws governing confidentiality of data that are applicable to DTC in connection with its collection and disclosure of data.

DTC believes that the rules and regulations applicable to DTC governing the use and disclosure of confidential information provide standards that are representative of those of the various regulatory bodies governing its Participants. As a result, DTC does not believe that the proposed rule change relating to the DTC Confidentiality Requirements would result in any change to DTC's practices relating to data protection and confidentiality of information provided by Participants.

(ii) Participant Confidentiality Requirements

Historically, DTC has generally not provided, nor been requested to provide, information that contains confidential or proprietary information of DTC or its affiliates to its Participants except for information necessary for Participants and their service providers and service bureaus to connect to DTC and to participate in the services that DTC offers to its Participants. While certain information is protected by intellectual property rights of DTC and its affiliates under applicable intellectual property laws, such as copyright laws and trademark laws, the Rules do not include any express obligations for Participants to protect confidential information received by them from DTC or its affiliates.

In connection with the development of cyber and information security programs pursuant to applicable regulatory requirements by Participants, DTC and its parent company, The Depository Trust & Clearing Corporation

("DTCC"), have received an increasing number of requests from Participants for confidential and proprietary information of DTC and DTCC.⁶ This includes, for example, information regarding DTCC's network operations and data security practices, legal settlements, and other information. Additionally, in the event there is a cyber incident relating to a Participant, DTC or DTCC may be requested to disclose confidential information regarding its cyber threat indicators, sources of cyber threat information, or other information and actions taken related to a cyber event.

In order to provide for contractual protections for such confidential information of DTCC, DTC and DTCC's other subsidiaries, DTC is proposing to add provisions to the Rules that would require Participants to maintain confidential information of DTC and its affiliates that DTC provides to such Participants in confidence and not to disclose such confidential information except as necessary to perform such Participant's obligations under DTC's Rules or as otherwise required by applicable law ("Participant Confidentiality Requirements"). The Participant Confidentiality Requirements would provide that in the event of a breach of the Participant Confidentiality Requirements, DTC or DTCC would be entitled to seek any temporary or permanent injunctive or other equitable relief in addition to any monetary damages under the Rules. In addition, as with any failure to comply with its Rules, DTC would have the ability to impose other disciplinary proceedings or restrictions on access to services as provided in the Rules for failure to comply with the Participant Confidentiality Requirements.

(iii) Market Disruption Events

Rule 38 (Market Disruption and Force Majeure)⁷ (the "Force Majeure Rule") contains provisions that identify the events or circumstances that would be considered a Market Disruption Event, including, for example, events that lead to the suspension or limitation of trading or banking in the markets in which DTC operates, or the unavailability or failure of any material

⁶ DTCC provides a set of core business processes for DTC and DTCC's other subsidiaries, including the technology systems and networks that provide connectivity between DTC and its participants and that provide the ability of DTC to provide the services as required under its Rules. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides relevant services to DTC and DTCC's other subsidiaries.

⁷ Rule 38, *supra* note 3.

payment, bank transfer, wire or securities settlement systems.⁸ Under the Force Majeure Rule, during the pendency of a Market Disruption Event, DTC would be entitled to (i) suspend the provision of any or all services and (ii) take, or refrain from taking, or require Members to take, or refrain from taking, any actions DTC considers appropriate to address, alleviate, or mitigate the event and facilitate the continuation of DTC's services as may be practicable.⁹

Section 2 of the Force Majeure Rule provides that the Board of Directors may determine the existence of a Market Disruption Event and the actions to be taken in response thereto.¹⁰ However, if the Board of Directors is unable to convene, the Force Majeure Rule provides that certain officers may make such determination, on an interim basis, which determination is then ratified, modified or rescinded as soon as practicable by the Board of Directors. The officers that may make such determination are all senior executive officers of DTC: Chief Executive Officer, Chief Financial Officer, Group Chief Risk Officer and General Counsel.

The proposed rule change would add two senior executive officers of DTC, the Chief Information Officer and the Head of Clearing Agency Services, to the list of officers that could make such determination if the Board of Directors is unable to convene. These two officers, like the other senior executive officers currently listed in the Rules, maintain senior executive level positions at DTC, oversee divisions of DTC, and hold positions at DTC that would provide them a necessary global view into DTC's operations and systems to enable them to determine the existence of a Market Disruption Event in the event that the Board of Directors is unable to convene. Adding these two additional officers would facilitate DTC's ability to implement its emergency procedures in the event of a Market Disruption Event.

(iv) Systems Disconnect: Threat of Significant Impact to DTC's Systems

The proposed rule change would add a new Rule 38(A) (Systems Disconnect: Threat of Significant Impact to the Corporation's Systems) ("Systems Disconnect Rule") that would address situations in which DTC determines it is necessary for DTC to disconnect a single or limited number of Participants, or third party service providers, or service bureaus used by Participants to connect

⁸ *Id.*

⁹ *Id.*

¹⁰ Section 2 of Rule 38, *id.*

to DTC¹¹ (collectively, “DTCC Systems Participants”) from DTC’s systems or network due to an imminent threat of harm to DTC’s or DTCC’s systems. The imminent threat could be the result of a system disruption or cyber incident applicable to the DTCC Systems Participants. This would allow DTCC to work with the affected Participants while protecting DTC, its systems and its other Participants.

The proposed Systems Disconnect Rule would be structured similarly to the Force Majeure Rule. The Systems Disconnect Rule would address DTC’s authority to take certain actions upon the occurrence, and during the pendency, of a Major Event. A “Major Event” would be defined as the happening of one or more Systems Disruption(s) (as defined below) that is reasonably likely to have a significant impact on DTC’s operations, including the DTCC Systems (as defined below), that affect the business, operations, safeguarding of securities or funds, or physical functions of DTC, Participants and/or other market participants. “Systems Disruption” would be defined as the unavailability, failure, malfunction, overload, or restriction (whether partial or total) of a DTCC Systems Participant’s systems that disrupts or degrades the normal operation of such DTCC Systems Participant’s systems; or anything that impacts or alters the normal communication, or the files that are received, or information transmitted, to or from the DTCC Systems. “DTCC Systems” would be defined as the systems, equipment and technology networks of DTCC, DTC and/or their Affiliates,¹² whether owned, leased, or licensed, software, devices, IP addresses or other addresses or accounts used in connection with providing the services set forth in the Rules, or used to transact business or to manage the connection with DTC.

The proposed Systems Disconnect Rule would allow DTC to mitigate the effect of such events by facilitating the continuity of services (or, if deemed necessary, the temporary suspension of services). To that end, under the proposed Systems Disconnect Rule, DTC would be entitled, during the pendency of a Major Event, to (1)

disconnect a DTCC Systems Participant’s systems from the DTCC Systems, (2) suspend the receipt and/or transmission of files or communications to or from the DTCC Systems Participant to the DTCC Systems and/or (3) take, or refrain from taking, or require a DTCC Systems Participant to take or refrain from taking, any actions that DTC considers appropriate to prevent, address, correct, mitigate or alleviate the Major Event and facilitate the continuation of services as may be practicable and, in that context, issue instructions to the DTCC Systems Participant.

The proposed Systems Disconnect Rule would define the governance procedures for how DTC would determine whether, and how, to implement the provisions of the rule. A determination that a Major Event has occurred could be made by the same officers with delegated authority under the Force Majeure Rule as discussed above (an “Officer Major Event Action”). Following this determination, any management committee on which all of the foregoing officers serve would convene, and DTC would convene a Board of Directors meeting as soon as practicable thereafter, and in any event within five Business Days following such determination, in each case, to ratify, modify, or rescind the Officer Major Event Action. The proposed Systems Disconnect Rule would require Participants to notify DTC immediately upon becoming aware of a Major Event, and, likewise, would require DTC to promptly notify the DTCC Systems Participant(s) of any action DTC takes or intends to take with respect to such DTCC Systems Participant(s) pursuant to the proposed rule.

Finally, the Systems Disconnect Rule would address certain miscellaneous matters including: (i) A limitation of liability for any failure or delay in performance, in whole or in part of DTC’s obligations under the Rules, arising out of or related to a Major Event, (ii) a statement that the power of DTC to take any action pursuant to the Systems Disconnect Rule also includes the power to repeal, rescind, revoke, amend or vary such action, (iii) a statement that the powers of DTC pursuant to the Systems Disconnect Rule shall be in addition to, and not in derogation of, authority granted elsewhere in the Rules to take action as specified therein, (iv) a requirement that Participants shall keep any DTCC Confidential Information (as defined below) provided to them by DTC and/or in connection with a Major Event confidential and (v) a statement that in the event of any conflict between the

provisions of the Systems Disconnect Rule and any other Rules or Procedures, the provisions of the Systems Disconnect Rule would prevail.

(v) Proposed Rule Changes

The proposed rule change would amend the Rules to make the following changes to implement the changes discussed above:

DTC Confidentiality Requirements Changes

The proposed rule change would amend the DTC Confidentiality Requirements in two paragraphs in Section 1 of Rule 2,¹³ to state as follows:

. . . any non-public information furnished to the Corporation pursuant to this Rule shall be held in confidence as may be required under the laws, rules and regulations applicable to the Corporation that relate to the confidentiality of records.

As discussed above, the proposed language is intended to provide one standard that DTC would apply uniformly to all Participants, which assures Participants that such information would be held in confidence with appropriate controls. DTC would add “non-public” when describing the information that is subject to the DTC Confidentiality Requirements to make it clear that such requirements would only apply to information that is not public.

Certain Rules relating to DTC Confidentiality Requirements would also include language relating to Participant Confidentiality Requirements as described below.

Participant Confidentiality Requirements

In order to provide for Participant Confidentiality Requirements, DTC would add a provision at the end of Section 1 of Rule 2¹⁴ to state that each applicant and Participant shall maintain DTCC Confidential Information in confidence to the same extent and using the same means it uses to protect its own confidential information, but no less than a reasonable standard of care, and shall not use DTCC Confidential Information or disclose DTCC Confidential Information to any third party except as necessary to perform its obligations under the Rules or as otherwise required by applicable law. DTC would add a new definition of DTCC Confidential Information in Section 1 of Rule 1¹⁵ to provide that

¹¹ Some Participants use third parties to connect to DTC’s systems and/or to send data to DTC and receive data from DTC on the Participant’s behalf. Such third parties are referred to as “service providers” or “service bureaus” herein.

¹² “Affiliate” would be defined as a Person that controls or is controlled by or is under common control with another Person. Control of a Person means the direct or indirect ownership, or power to vote more than 50% of any class of the voting securities or other voting interests of such Person.

¹³ Section 1 of Rule 2, *supra* note 3.

¹⁴ Section 1 of Rule 2, *supra* note 3.

¹⁵ Section 1 of Rule 1, *supra* note 3.

“DTCC Confidential Information” would mean all non-public information provided by DTCC and/or DTC that (i) is marked or otherwise identified in writing prior to disclosure to the recipient as confidential, (ii) is designated by DTCC or DTC as confidential, or (iii) the recipient knows or, under the circumstances surrounding disclosure, ought to reasonably know is confidential. DTC would also add a definition of DTCC in Section 1 of Rule 1 and remove a corresponding definition in Rule 32(A)¹⁶ since it would be defined in Section 1 of Rule 1.

DTC would also add a statement in the provision relating to Participant Confidentiality Requirements that each applicant and Participant acknowledges that a breach of its confidentiality obligations under the Rules may result in serious and irreparable harm to DTC and/or DTCC for which there is no adequate remedy at law. In the event of such a breach by the applicant or Participant, DTC and/or DTCC would be entitled to seek any temporary or permanent injunctive or other equitable relief in addition to any monetary damages.

Force Majeure Rule Officer Additions

The proposed rule change would add the Chief Information Officer and the Head of Clearing Agency Services to the list of officers that could make a determination of a Market Disruption Event if the Board of Directors is unable to convene in Rule 38.¹⁷

Systems Disconnect Rule

The proposed rule change would add a new Rule 38(A) entitled “Systems Disconnect: Threat of Significant Impact to the Corporation’s Systems” that would address situations in which DTC determines it is necessary for DTC to disconnect a DTCC Systems Participant or DTCC Systems Participants from DTC’s systems or network due to an imminent threat of harm to DTC’s or DTCC’s systems consistent with the description above. The proposed Systems Disconnect Rule would include new definitions for “DTCC Systems,” “DTCC Systems Participant,” “Major Event” and “Systems Disruption” consistent with the descriptions of the Systems Disconnect Rule above.

2. Statutory Basis

DTC believes that the proposal is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered

clearing agency. In particular, DTC believes that each of the proposed rule changes is consistent with Section 17A(b)(3)(F) of the Act,¹⁸ and Rules 17Ad-22(e)(1) and (e)(21)¹⁹ promulgated under the Act. In addition, DTC believes that the proposed changes to add the two senior executive officers in the Force Majeure Rule and to add the proposed Systems Disconnect Rule are consistent with Rules 17Ad-22(e)(2) and (e)(17) under the Act.²⁰

Section 17A(b)(3)(F)

Section 17A(b)(3)(F) of the Act²¹ requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible, and to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.

DTC believes that the proposed changes revising the DTC Confidentiality Requirements and adding the Participant Confidentiality Requirements are each consistent with this provision of the Act. The proposed revisions to the DTC Confidentiality Requirements are consistent with this provision because the proposed revisions would provide a clear and consistent standard relating to how DTC holds the information furnished by Participants pursuant to Section 1 of Rule 2.²² The confidential information that DTC receives pursuant to this rule is used by DTC to determine whether to admit a Participant, to continue to allow such Participant to be a Participant, or to better understand the risks relating to each Participant. Providing a clear and consistent standard would facilitate this process by allowing Participants to better understand DTC’s obligations with respect to such information and providing a uniform obligation for DTC with respect to such information. DTC believes that facilitating the ability of DTC to evaluate Participants would promote the prompt and accurate clearance and settlement of securities transactions by DTC. As such, DTC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act.²³

DTC also believes that the proposed rule change adding the Participant

Confidentiality Requirements is consistent with this provision of the Act because the proposed revisions to the Participant Confidentiality Requirements would provide a clear and consistent contractual obligation for applicants and Participants who are requesting confidential information from DTC. Having clear and consistent Rules would help applicants and Participants to better understand their rights and obligations regarding DTC’s clearance and settlement services. The information requested by applicants and Participants that would be subject to the Participant Confidentiality Requirements would be used by applicants and Participants to determine whether to participate in DTC’s services, DTC system requirements and DTC system safeguards. DTC believes that when Participants better understand their rights and obligations regarding DTC’s clearance and settlement services, they can better act in accordance with the Rules. DTC believes that better enabling Participants to comply with the Rules would promote the prompt and accurate clearance and settlement of securities transactions by DTC. As such, DTC believes the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act.²⁴

DTC believes that the proposed changes to add the two officers to make a determination of a Market Disruption Event and to add the Systems Disconnect Rule are also consistent with this provision of the Act because those changes would enhance and streamline DTC’s ability to take necessary actions in the event of a Market Disruption Event or a Major Event. Improving the ability of DTC to react to a Market Disruption Event or a Major Event would allow DTC to protect its Participants and their ability to promptly and accurately clear and settle securities transactions, and allow DTC to safeguard securities and funds that are in its custody or control. In particular, allowing two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to DTC while maintaining proper risk controls and improve the ability of DTC to act in the event of a Market Disruption Event. Also, providing for the ability of DTC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such

¹⁶ Rule 32(A), *supra* note 3.

¹⁷ Rule 38, *supra* note 3.

¹⁸ 15 U.S.C. 78q-1(b)(3)(F).

¹⁹ 17 CFR 240.17Ad-22(e)(1) and (e)(21).

²⁰ 17 CFR 240.17Ad-22(e)(2) and (e)(17).

²¹ 15 U.S.C. 78q-1(b)(3)(F).

²² Section 1 of Rule 2, *supra* note 3.

²³ 15 U.S.C. 78q-1(b)(3)(F).

²⁴ *Id.*

other actions as are necessary to protect DTC and its Participants would, in each case, provide additional tools for DTC in the event of a Major Event.

Improving the governance around the determination of a Market Disruption Event, and the implementation of procedures allowing DTC to disconnect a DTCC Systems Participant or DTCC Systems Participants from DTC's systems or network due to an imminent threat of harm, would improve DTC's ability to address and minimize losses to DTC and its Participants. Risks, threats and potential vulnerabilities due to a Market Disruption Event or a Major Event could impact DTC's ability to clear and settle securities transactions, or to safeguard the securities and funds which are in its custody or control or for which it is responsible. In addition, providing governance around the ability to disconnect a DTCC Systems Participant that is having a systems disruption that could disrupt the ability of DTC or other DTCC Systems Participants from using DTC's systems would remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. Although disconnecting or limiting the service of a DTCC Systems Participant in the event of a Major Event would likely be an impediment to such DTCC Systems Participant, improving DTC's ability to address and minimize losses to DTC and its Participants, and reducing risks, threats and potential vulnerabilities due to a Major Event that could impact DTC's ability to clear and settle securities transactions, or to safeguard the securities and funds which are in its custody or control or for which it is responsible, would be consistent with Section 17A(b)(3)(F) of the Act.²⁵

Therefore, by implementing tools that would help to mitigate these risks, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, assure the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible, and remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.²⁶

Rule 17Ad-22(e)(1)

In addition, the proposed rule change is designed to be consistent with Rule

17Ad-22(e)(1) promulgated under the Act,²⁷ which requires DTC to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent and enforceable legal basis for each aspect of its activities in all relevant jurisdictions.

Establishing clear and consistent rules for each Participant with respect to the DTC Confidentiality Requirements would allow DTC to maintain one confidentiality standard for all Participants rather than maintaining potentially different confidentiality standards for Participants based on the various, unrelated regulatory bodies governing such Participants. In addition, setting forth a clear contractual obligation relating to Participant Confidentiality Requirements would enhance the understanding of the Participants receiving information from DTC and allow DTC to treat Participants equally with respect to how the information furnished to Participants should be protected by the Participants.

Adding the two officers to make a determination of a Market Disruption Event and adding the Systems Disconnect Rule are also consistent with Rule 17Ad-22(e)(1) under the Act because those changes would describe the circumstances under which DTC could take actions in the event of a Market Disruption Event or a Major Event that are necessary to protect DTC and its Participants. Providing clear guidelines with respect to Market Disruption Events and Major Events would allow DTC Participants to understand the rights and obligations of the Participants in the event of a Market Disruption Event or a Major Event.

Therefore, by establishing uniform and clear standards with respect to its receipt and furnishing of confidential information, and by providing clear rights and obligations of DTC and its Participants with respect to Market Disruption Events and Major Events, DTC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(1) promulgated under the Act.²⁸

Rule 17Ad-22(e)(21)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(21) promulgated under the Act,²⁹ which requires DTC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and

effective in meeting the requirements of its Participants and the markets it serves. The proposed rule change would streamline the DTC Confidentiality Requirements by providing that DTC would apply one standard for all Participants relating to confidential information sent to DTC by Participants, which would enhance (i) efficiency by avoiding applying varying standards of confidentiality based on the rules and regulations of the varying regulatory bodies that regulate the Participants, and (ii) effectiveness by reducing potential conflicts of laws and providing equal treatment to Participants relating to such confidential information.

The addition of the Participant Confidentiality Requirements would also provide a uniform and easily discernable requirement for all Participants with respect to confidential information provided by DTC allowing DTC to provide necessary information to such Participants in a safe and efficient manner. Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to DTC while maintaining proper risk controls and improve the ability of DTC to act quickly, efficiently and effectively in a Market Disruption Event to address and minimize losses. Also, providing for the ability of DTC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect DTC and its Participants would, in each case, provide additional tools for DTC in the event of a Major Event and improve DTC's ability to act quickly, efficiently and effectively in the event of a Major Event to address and minimize losses.

Therefore, by establishing a more efficient and effective process for the treatment of confidential language, and establishing procedures designed to improve DTC's ability to act quickly, efficiently and effectively in the event of a Market Disruption Event and a Major Event, DTC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(21) promulgated under the Act.³⁰

Rule 17Ad-22(e)(2)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(2) promulgated under the

²⁵ *Id.*

²⁶ *Id.*

²⁷ 17 CFR 240.17Ad-22(e)(1).

²⁸ *Id.*

²⁹ 17 CFR 240.17Ad-22(e)(21).

³⁰ *Id.*

Act,³¹ which requires DTC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and that specify clear and direct lines of responsibility.

Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to DTC while maintaining proper risk controls, and improve the ability of DTC to act quickly, efficiently and effectively in a Market Disruption Event and mitigate any impact from such Market Disruption Event. Adding these officers to the governance procedures relating to a determination of a Market Disruption Event would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Market Disruption Event, consistent with Rule 17Ad-22(e)(2) under the Act.³²

Adding the governance procedures relating to making a determination of a Major Event in the Systems Disconnect Rule is also consistent with Rule 17Ad-22(e)(2) promulgated under the Act.³³ Identifying the officers that have the ability to determine if there is a Major Event, and providing for the ability of any management committee on which all of such officers serve and the Board of Directors to ratify, modify or rescind any determination of a Major Event by an officer would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Major Event, consistent with Rule 17Ad-22(e)(2).³⁴

Rule 17Ad-22(e)(17)

In addition, the proposed rule change is designed to be consistent with Rule 17Ad-22(e)(17)(i) promulgated under the Act,³⁵ which requires DTC to establish, implement, maintain and enforce written policies and procedures reasonably designed to manage the covered clearing agency's operational risks by identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls.

Adding two additional officers that are able to make an interim determination of a Market Disruption Event in the event that the Board of Directors is unable to convene would add additional flexibility and tools to DTC while maintaining proper risk controls and improve the ability of DTC to act quickly, efficiently and effectively in a Market Disruption Event and mitigate any impact from such Market Disruption Event. Also, providing for the ability of DTC to disconnect DTCC Systems Participants, suspend the receipt or transmission of files or communications to or from a DTCC Systems Participant, and/or require the DTCC Systems Participant to take such other actions as are necessary to protect DTC and its Participants would, in each case, provide additional tools for DTC in the event of a Major Event and improve DTC's ability to act quickly, efficiently and effectively in the event of a Major Event and mitigate any impact from such Major Event.

Therefore, by providing clear, efficient procedures of DTC and its Participants with respect to Market Disruption Events and Major Events that help identify and mitigate operational risks, DTC believes that the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(17)(i) promulgated under the Act.³⁶

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe that the proposed changes relating to the DTC Confidentiality Requirements would have any impact on competition. These changes would provide one standard for how DTC treats Participant information furnished subject to the DTC Confidentiality Requirements but would not affect the information that the Participants are required to provide or affect the manner in which the Participants must provide the information. As such, DTC believes these proposed rule changes would not have any impact on competition.

DTC does not believe the proposed changes relating to adding Participant Confidentiality Requirements would have any impact on competition. Although the addition of the Participant Confidentiality Requirements would be adding obligations on Participants with respect to how they treat confidential or proprietary information of DTC or its affiliates, such obligations would be minimal because DTC would only require that such Participants hold such confidential information using the same means they use to protect their own

confidential information but not less than a reasonable standard of care. The use of this standard would protect DTC by providing a clear legal obligation to protect such information but would not be burdensome or expensive for Participants, and therefore DTC believes that it would not have any impact on competition.

DTC does not believe the changes relating to adding the two officers to make a determination of a Market Disruption Event would have any impact on competition. The proposed rule change would add two senior executive officers of DTC, the Chief Information Officer and the Head of Clearing Agency Services, to the list of officers that could make a determination of a Market Disruption Event if the Board of Directors is unable to convene. Such addition would provide additional officers who could determine whether there is a Market Disruption Event but would not otherwise affect the rights of Participants or DTC in the determination of a Market Disruption Event or if a Market Disruption Event is declared. Therefore, DTC does not believe that the addition of the two officers would have any impact on competition.

DTC does not believe that the changes relating to adding the Systems Disconnect Rule would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act.³⁷ To the extent that DTC determines that there is a Major Event, it could take or refrain from taking actions, or require Participants to take or refrain from taking actions, that could burden competition because such requirements could cause Participants to incur additional costs, allow DTC to suspend services or communications, or disconnect a DTCC Systems Participant from the DTCC Systems. DTC believes such burden on competition could be significant but would be both necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act,³⁸ for the reasons described below.

DTC believes that the proposed changes to add the Systems Disconnect Rule are necessary in furtherance of the purposes of Section 17A(b)(3)(F) of the Act,³⁹ and Rules 17Ad-22(e)(1), (e)(2), (e)(17) and (e)(21) promulgated under the Act.⁴⁰ The proposed changes to add the Systems Disconnect Rule would (i)

³¹ 17 CFR 240.17Ad-22(e)(2).

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ 17 CFR 240.17Ad-22(e)(17)(i).

³⁶ *Id.*

³⁷ 15 U.S.C. 78q-1(b)(3)(I).

³⁸ *Id.*

³⁹ 15 U.S.C. 78q-1(b)(3)(F).

⁴⁰ 17 CFR 240.17Ad-22(e)(1), (e)(2), (e)(17) and (e)(21).

improve the ability of DTC to react to a Major Event allowing DTC to protect itself and its Participants and their ability to promptly and accurately clear and settle securities transactions, and allow DTC to safeguard securities and funds that are in its custody or control, consistent with the requirements of Section 17A(b)(3)(F) of the Act,⁴¹ (ii) provide clear guidelines with respect to Major Events that would allow Participants to understand the rights and obligations of the Participants and DTC in the event of a Major Event, consistent with Rule 17Ad-22(e)(1) promulgated under the Act,⁴² (iii) identify the officers that have the ability to determine if there is a Major Event, and provide for the ability of any management committee on which all of such officers serve, and the Board of Directors, to ratify, modify or rescind any determination of a Major Event by an officer, which would make such governance procedures clear and transparent, and specify clear and direct lines of responsibility with respect to the determination of a Major Event, consistent with Rule 17Ad-22(e)(2) promulgated under the Act,⁴³ (iv) improve the ability of DTC to act quickly, efficiently and effectively in the event of a Major Event, and mitigate any impact from such event by providing clear, efficient procedures of DTC and its Participants with respect to such event, consistent with the requirements of Rule 17Ad-22(e)(17)(i) promulgated under the Act⁴⁴ and (v) establish procedures designed to improve DTC's ability to act quickly, efficiently and effectively in the event of a Major Event, consistent with the requirements of Rule 17Ad-22(e)(21) promulgated under the Act.⁴⁵

In addition, DTC believes that the proposed changes to add the Systems Disconnect Rule are appropriate in furtherance of the Act. Such changes have been designed to improve the ability of DTC to act quickly, efficiently and effectively in the event of a Major Event, and mitigate any impact from such event while also providing the Participants clear guidelines with respect to such event to allow Participants to understand their rights and obligations. Such changes have also been designed to apply uniformly to all Participants in the event of a Major Event and should not affect DTC's day-to-day operations under normal circumstances, or in the management of

a typical Participant default scenario or non-default event.

Therefore, DTC does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.⁴⁶

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. DTC will notify the Commission of any written comments received by DTC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-DTC-2021-011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.
- All submissions should refer to File Number SR-DTC-2021-011. 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 DTC and on DTCC's website (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-DTC-2021-011 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁷

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-14797 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34324, File No. 812-15232]

Hartford Funds Exchange-Traded Trust, et al.

July 7, 2021.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c-1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under Section 12(d)(1)(f) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

⁴¹ 15 U.S.C. 78q-1(b)(3)(F).

⁴² 17 CFR 240.17Ad-22(e)(1).

⁴³ 17 CFR 240.17Ad-22(e)(2).

⁴⁴ 17 CFR 240.17Ad-22(e)(17)(i).

⁴⁵ 17 CFR 240.17Ad-22(e)(21).

⁴⁶ 15 U.S.C. 78q-1(b)(3)(I).

⁴⁷ 17 CFR 200.30-3(a)(12).

APPLICANTS: Hartford Funds Exchange-Traded Trust (the “Trust”), Hartford Funds Management Company, LLC (the “Adviser”), and ALPS Distributors, Inc. (the “Distributor”).

SUMMARY OF APPLICATION: Applicants request an order (“Order”) that permits: (a) The Funds (defined below) to issue shares (“Shares”) redeemable in large aggregations only (“creation units”); (b) secondary market transactions in Shares to occur at negotiated market prices rather than at net asset value; (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; and (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of creation units. The relief in the Order would incorporate by reference terms and conditions of the same relief of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (“Reference Order”).¹

FILING DATE: The application was filed on May 25, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission’s Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on August 2, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, *Secretarys-Office@sec.gov*. Applicants: Thomas R. Phillips, Esq., Hartford Funds Management Company, LLC, *thomas.phillips@hartfordfunds.com*.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, at (202) 551–6811 or Kaitlin C. Bottock, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission’s website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551–8090.

Applicants

1. The Trust is a statutory trust organized under the laws of Delaware and consists of, among other series, one or more series operating as a Fund. The Trust is registered as an open-end management investment company under the Act. Applicants seek relief with respect to Funds (as defined below), including the initial Fund (the “Initial Fund”). The Initial Fund will offer exchange-traded shares utilizing active management investment strategies as contemplated by the Reference Order.²

2. The Adviser, a Delaware limited liability company, will be the investment adviser to the Initial Fund. Subject to approval by the Trust’s board of trustees, the Adviser (as defined below) will serve as investment adviser to the Funds. The Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (“Advisers Act”). The Adviser may enter into sub-advisory agreements with other investment advisers to act as sub-advisers with respect to a Fund (each a “Sub-Adviser”). Any Sub-Adviser to a Fund will be registered under the Advisers Act.

3. The Distributor is a Colorado corporation and a broker-dealer registered under the Securities Exchange Act of 1934, as amended, and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser and/or Sub-Adviser (included in the term

“Distributor”). Any Distributor will comply with the terms and conditions of the Order.

Applicants’ Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act and under Section 12(d)(1)(J) of the Act for an exemption from Sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested Order would permit applicants to offer Funds that operate as contemplated by the Reference Order. Because the relief requested is the same as certain of the relief granted by the Commission under the Reference Order and because the Adviser has entered into a licensing agreement with Fidelity Management & Research Company, or an affiliate thereof, in order to offer Funds that operate as contemplated by the Reference Order,³ the Order would incorporate by reference the terms and conditions of the same relief of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term “Adviser”); (b) offers exchange-traded shares utilizing active management investment strategies as contemplated by the Reference Order; and (c) complies with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order (each such company or series and the Initial Fund, a “Fund”).⁴

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy

¹ Fidelity Beach Street Trust, et al., Investment Company Act Rel. Nos. 33683 (Nov. 14, 2019) (notice) and 33712 (Dec. 10, 2019) (order). Applicants are not seeking relief under Section 12(d)(1)(J) of the Act for an exemption from Sections 12(d)(1)(A) and 12(d)(1)(B) of the Act (the “Section 12(d)(1) Relief”), and relief under Sections 6(c) and 17(b) of the Act for an exemption from Sections 17(a)(1) and 17(a)(2) of the Act relating to the Section 12(d)(1) Relief, except as necessary to allow a Fund’s receipt of Representative ETFs included in its Tracking Basket solely for purposes of effecting transactions in Creation Units (as these terms are defined in the Reference Order), notwithstanding the limits of Rule 12d1–4(b)(3). Accordingly, to the extent the terms and conditions of the Reference Order relate to such relief, they are not incorporated by reference herein other than with respect to such limited exception.

² To facilitate arbitrage, among other things, each day a Fund will publish a basket of securities and cash that, while different from the Fund’s portfolio, is designed to closely track its daily performance.

³ Certain aspects of how the Funds will operate (as described in the Reference Order) are the intellectual property of Fidelity Management & Research Company (or its affiliates).

⁴ All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order.

and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Applicants submit that for the reasons stated in the Reference Order the requested relief meets the exemptive standards under sections 6(c), 17(b) and 12(d)(1)(J) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-14788 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92344; File No. SR-NASDAQ-2021-054]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Modify Listing Rule IM-5101-2 To Permit an Acquisition Company To Contribute a Portion of Its Deposit Account to Another Entity in a Spin-Off or Similar Corporate Transaction

July 7, 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 June 24, 2021, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Listing Rule IM-5101-2 to permit a SPAC to contribute a portion of the amount held in its deposit account to a deposit account of a new SPAC and spin off the new SPAC to its shareholders.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to modify IM-5101-2 to allow an acquisition company listed under that rule to contribute a portion of the amount held in its deposit account to a deposit account of a new acquisition company and spin off the new acquisition company to its shareholders in certain situations where the new acquisition company will be subject to all of the same requirements as the original acquisition company.

Generally, Nasdaq will not permit the initial or continued listing of a company that has no specific business plan or that has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies. In 2008, Nasdaq adopted a rule to allow such companies to list if they meet all applicable initial listing requirements, as well as additional conditions designed to provide investor protections to address specific concerns about the structure of such companies (“acquisition companies” or “SPACs”).³ These additional conditions generally

require, among other things, that at least 90% of the gross proceeds from the initial public offering must be deposited in a “deposit account,” as that term is defined in the rule, and that the SPAC complete within 36 months, or a shorter period identified by the SPAC, one or more business combinations having an aggregate fair market value of at least 80% of the value of the deposit account at the time of the agreement to enter into the initial combination.

When a SPAC conducts its initial public offering, it raises the amount of capital that it estimates will be necessary to finance a subsequent business combination with its ultimate target. However, because a SPAC cannot identify or select a specific business combination target at the time of its IPO, it often turns out that the amount raised is not optimal for the needs of a specific target. This has resulted in the inefficient, current practice of SPAC sponsors creating multiple SPACs of different sizes at the same time, with the intention to use the SPAC that is closest in size to the amount a particular target needs. This practice creates the potential for conflicts between the multiple SPACs (each of which has different shareholders) and still fails to optimize the amount of capital that would benefit the SPAC's public shareholders and a business combination target. Moreover, this creates the need for repetitive action throughout the ecosystem, including the filing and SEC review of multiple registration statements and periodic reports, formation of multiple boards of directors, multiple audits and multiple company listings. This practice also can lead to confusion amongst investors.

Accordingly, Nasdaq proposes to modify IM-5101-2 to permit a more efficient structure whereby an acquisition company can raise in its initial public offering the maximum amount of capital it anticipates it may need for a business combination transaction and then “rightsized” itself by contributing any amounts not needed to a new SPAC (the “SpinCo SPAC”), and spinning off this SpinCo SPAC to its shareholders. The SpinCo SPAC will be subject to all the provisions of IM-5101-2 in the same manner, and subject to the same timeframes, as the original SPAC.

It is expected that the new structure will be implemented in the following manner. If the listed SPAC (the “Original SPAC”) determines that it will not need all of the cash in its deposit account for its initial business combination, it will designate the excess cash for a new deposit account held by a new SPAC, the SpinCo SPAC (such

³ IM-5101-2. See Securities Exchange Act Release No. 58228 (July 25, 2008), 73 FR 44794 (July 31, 2008) (adopting the predecessor to IM-5101-2).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

amount, the “SpinCo Deposit Account,” and the amount retained in the deposit account of the Original SPAC, the “Retained SPAC Deposit Account”), which will be spun off to the Original SPAC’s shareholders as described below. Until the spin-off described below, the amount designated for the SpinCo Deposit Account must continue to be held for the benefit of the shareholders of the Original SPAC. Following the spin-off, the SpinCo Deposit Account will be subject to the same requirements as the deposit account of the Original SPAC.

The SpinCo SPAC will file a registration statement under the Securities Act of 1933 for purposes of effecting the spin-off of the SpinCo SPAC. Prior to the effectiveness of the registration statement, the Original SPAC will provide its public shareholders through one or more corporate transactions with the opportunity to redeem a pro rata amount of their holdings equal to the amount of the SpinCo Deposit Account divided by the per share amount in the Original SPAC’s deposit account (the “redemption price”).⁴

After completing the tender offer and effectiveness of the SpinCo SPAC’s registration statement, the Original SPAC will contribute the SpinCo Deposit Account to a deposit account held by the SpinCo SPAC in exchange for shares or units of the SpinCo SPAC, which the Original SPAC will then distribute to its public shareholders on a pro rata basis through one or more corporate transactions pursuant to the SpinCo SPAC’s effective registration statement.

The Original SPAC will then continue to operate as a SPAC until it completes its business combination and will offer redemption rights to its public shareholders in connection with that business combination in the same manner as a traditional SPAC. The SpinCo SPAC will operate in the same manner as a traditional SPAC, except that it could effect a spin-off prior to its business combination like the Original SPAC. If it does not elect to effect a spin-off, the SpinCo SPAC will proceed to complete an initial business combination and offer redemption rights in connection therewith like a traditional SPAC.

Nasdaq proposes adopting a new subsection at IM-5101-2(f) which will

specifically permit this type of transaction by allowing the Original SPAC to contribute a portion of the amount held in the deposit account to the deposit account of SpinCo SPAC in a spin-off or similar corporate transaction where all of the conditions described below are satisfied:

(i) The public shareholders of the Original SPAC receive a pro rata interest in the SpinCo SPAC, except to the extent that they have elected to redeem a portion of their shares of the Original SPAC in lieu of being entitled to receive shares or units in the SpinCo SPAC;

(ii) public shareholders must have the right to convert or redeem their shares of common stock into a pro rata share of the aggregate amount then in the deposit account (net of taxes payable and amounts distributed to management for working capital purposes) before the first business combination, with part of such conversion or redemption able to be fulfilled through a redemption (including by means of a tender offer) in lieu of being entitled to receive shares or units in the spin-off of a SpinCo SPAC;

(iii) the amount distributed to the SpinCo SPAC must remain in the SpinCo Deposit Account for the benefit of the shareholders of the SpinCo SPAC in the same manner applicable to the Original SPAC as described in IM-5101-2(a);

(iv) the SpinCo SPAC must meet all applicable initial listing requirements, as well as the conditions described in IM-5101-2(a) through (e);

(v) in the case of the SpinCo SPAC, and any additional entities spun off from the SpinCo SPAC, each of which will also be considered a SpinCo SPAC, the 36-month period described in IM-5101-2(b) (or such shorter period that the original SPAC specifies in its registration statement) will be calculated based on the date of effectiveness of the Original SPAC’s IPO registration statement; and

(vi) in the aggregate, through one or more opportunities by the Original SPAC and one or more SpinCo SPACs, public shareholders will have the ability to convert or redeem shares, or receive amounts upon liquidation, for the full amount of the deposit account established by the Original SPAC as described in IM-5101-2(a) (excluding any deferred underwriters fees and taxes payable on the income earned on the deposit account).

Proposed IM-5101-2(f) would further provide that, for purposes of IM-5101-2(b), the Original SPAC must complete one or more business combinations with an aggregate fair market value of at least 80% of the aggregate amount remaining

in the Retained SPAC Deposit Account at the time of its agreement to enter into its initial combination. Similarly, a SpinCo SPAC must complete one or more business combinations with an aggregate fair market value of at least 80% of the aggregate amount remaining in the SpinCo Deposit Account at the time of its agreement to enter into its initial combination after giving effect to its contribution to a subsequent SpinCo SPAC, if any.

In addition, proposed IM-5101-2(f) would provide that, for purposes of IM-5101-2(d) and (e), the right to convert and opportunity to redeem shares of common stock on a pro rata basis, respectively, will, in the case of the Original SPAC, be deemed to apply to the aggregate amount remaining in the Retained SPAC Deposit Account, and, in the case of the SpinCo SPAC, be deemed to apply to the aggregate amount in the SpinCo Deposit Account. Under IM-5101-2(c), a majority of the Original SPAC’s independent directors must approve its business combination and a majority of the independent directors of the SpinCo SPAC must approve the SpinCo SPAC’s business combination.

In this manner, the structure allows public shareholders an additional, early redemption opportunity with respect to a portion of their holdings, before the time they would be able to do so in a traditional SPAC, and public shareholders would maintain the ability to redeem the portion of their investment attributable to each specific acquisition after reviewing all disclosure with respect to that acquisition. All other protections contained under IM-5101-2 would continue to apply, with adjustments only to reflect the potential for a spin-off of a new SPAC that is subject to all of the requirements of IM-5101-2. Moreover, the proposed structure would also provide shareholders the opportunity to invest with a sponsor without spreading that investment across the sponsor’s multiple SPACs.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁶ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

⁴ This redemption could occur, for example, through a partial cash tender offer for shares of the Original SPAC pursuant to Rule 13e-4 and Regulation 14E of the Securities Exchange Act of 1934, and the redemption may be of a separate class of shares distributed to unitholders of the Original SPAC for the purpose of facilitating the redemption.

establishing the means through which a SPAC can complete more than one business combination resulting in separate operating companies.

The Commission has previously concluded that listing an acquisition company that satisfies the requirements of Nasdaq IM-5101-2 is consistent with the investor protection goals of the Exchange Act.⁷ The proposed rule change will extend these important investor protections to a new structure that addresses inefficiencies and potential conflicts of interest in the SPAC market. Specifically, as proposed, a SpinCo SPAC will be required to satisfy all applicable initial listing requirements, like any other SPAC listing on Nasdaq. In addition, the provisions of IM-5101-2(a) will apply to the SpinCo SPAC in the same manner as they apply to any other SPAC, except the deposit account will be contributed to the SpinCo SPAC by the Original SPAC.

The provisions of IM-5101-2(b) and IM-5101-2(d) or (e), as applicable, will also apply to each of the Original SPAC and the SpinCo SPAC in the proposed structure in the same manner as they apply to any other SPAC, except that the 80% test will be applied to the amount retained by the Original SPAC after public shareholders have had an initial, early redemption opportunity and the Original SPAC has contributed a portion of its deposit account to the SpinCo SPAC. The Exchange believes that this proposed difference does not adversely affect shareholders because the shareholders will still have the opportunity to redeem for the entire pro rata share of the trust account prior to completion of the business combination. The primary difference is that the redemption right may be effected through two decisions, one of which is accelerated to allow an earlier redemption than would be available to the public shareholders of a traditional SPAC and the other will come at the time of the business combination, just as in a traditional SPAC.

As with the existing rules, each business combination must be approved by the SPAC's independent directors, as required by IM-5101-2(c), and following each business combination, the combined company must satisfy all initial listing requirements, as required by IM-5101-2(d) or (e), respectively.

Accordingly, in this manner, the Exchange believes that the proposed rule change satisfies the requirements of Section 6(b)(5) of the Act in that it is designed 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.

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. The proposed rule would be available in a non-discriminatory way to any company satisfying its requirements, as well as all other applicable Nasdaq listing requirements. In addition, Nasdaq faces competition for listings but the proposed rule change does not impose any burden on the competition with other exchanges; any competing exchange could similarly adopt rules to allow listing SPACs using such a structure.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2021-054 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-NASDAQ-2021-054. 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-NASDAQ-2021-054, and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-14799 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

⁷ Securities Exchange Act Release No. 58228, *supra* note 3.

⁸ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92335; File No. SR–NYSEArca–2021–55]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rules 6.4–O To Limit Short Term Options Series Intervals

July 7, 2021.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on June 28, 2021, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 6.4–O (Series of Options Contracts Open for Trading) in connection with limiting the number of strikes listed for Short Term Option Series which are available for quoting and trading on the Exchange. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included

statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.4–O (Series of Options Open for Trading). Specifically, this proposal seeks to widen the intervals between strikes in order to limit the number of strikes listed for multiply listed equity options classes (excluding options on Exchange-Traded Funds (“ETFs”) and Index-Linked Securities (as described herein, *see infra* n. 13) within the Short Term Option Series program that have an expiration date more than 21 days from the listing date.

Background

Current Rule 6.4–O permits the Exchange, after a particular class of options has been approved for listing and trading on the Exchange, to open for trading series of options therein. The Exchange may list series of options for trading on a weekly,⁴ monthly⁵ or quarterly⁶ basis. Rule 6.4–O(a) sets forth

the intervals between strike prices of series of options on individual stocks generally⁷ and Rule 6.4–O, Commentary .07(e) specifically sets forth intervals between strike prices Short Term Option Series. Additionally, the Exchange may list series of options pursuant to the \$1 Strike Price Interval Program,⁸ the \$0.50 Strike Program,⁹ the \$2.50 Strike Price Program,¹⁰ and the \$5 Strike Program.¹¹ The Exchange’s proposal seeks to amend the listing of weekly series of options (*i.e.* Short Term Option Series) by adopting new Commentary .07(f) to Rule 6.4–O,¹² which widens the permissible intervals between strikes, thereby limiting the number of strikes listed, for multiplylisted [sic] equity options

⁷ The interval between strike prices of series of options on individual stocks may be \$2.50 or greater where the strike price is \$25 or less, provided however, that the Exchange may not list \$2.50 intervals below \$50 (*e.g.*, \$12.50, \$17.50) for any class included within the \$1 Strike Price Program, as detailed below in Rule 6.4–O, Commentary .04 if the addition of \$2.50 intervals would cause the class to have strike price intervals that are \$0.50 apart. For series of options on Exchange-Traded Fund Shares that satisfy the criteria set forth in Rule 5.3–O(g), the interval of strike prices may be \$1 or greater where the strike price is \$200 or less or \$5 or greater where the strike price is over \$200. Exceptions to the strike price intervals above are set forth in Rule 6.4–O, Commentary .05.

⁸ The \$1 Strike Interval Program is described within Rule 6.4–O, Commentary .04.

⁹ The \$0.50 Strike Program is described within Rule 6.4–O, Commentary .13.

¹⁰ The \$2.50 Strike Price Program is described within Rule 6.4–O, Commentary .03.

¹¹ The \$5 Strike Program is described within Rule 6.4–O, Commentary .10.

¹² As a result, the proposed rule change subsequently updates current Rule 6.4–O, Commentary .07(f) to (g). In this regard, the Exchange also proposes to update a cross-reference to this newly re-lettered paragraph .07(g) that appears in Rule 6.4–O, Commentary .07(a). *See* proposed Rule 6.4–O, Commentary .07(a).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ The weekly listing program is known as the Short Term Option Series Program and is described within Rule 6.4–O, Commentary .07.

⁵ The Exchange will open at least one expiration month for each class of options open for trading on the Exchange. *See* Rule 6.4–O(a). The monthly expirations are subject to certain listing criteria for underlying securities described within Rule 5.3–O. Monthly listings expire the third Friday of the month *See* The Options Clearing Corporation (“OCC”) By-Laws at Section 1.

⁶ The quarterly listing program is known as the Quarterly Options Series Program and is described within Rule 6.4–O, Commentary .08.

(excluding options on ETFs¹³ and Index-Linked Securities¹⁴ that have an

¹³ The term “ETF” (Exchange-Traded Fund) (or “Fund Shares”) has the same meaning as the term “exchange-traded fund” as defined in Rule 6c–11 under the Investment Company Act of 1940. See Rule 5.3–O(g). Securities deemed appropriate for options trading shall include shares or other securities (“Exchange-Traded Fund Shares” or “Fund Shares”) that are traded on a national securities exchange and are defined as an “NMS stock” in Rule 600(b)(47) of Regulation NMS, and that (i) represent an interest in a registered investment company organized as an open-end management investment company, a unit investment trust or a similar entity which holds securities and/or financial instruments, options on securities and indices, equity caps, collars and floors, swap agreements, forward contracts, repurchase agreements and reverse repurchase agreements (the “Financial Instruments”), and money market instruments, including, but not limited to, U.S. government securities and repurchase agreements (the “Money Market Instruments”) constituting or otherwise based on or representing an investment in an index or portfolio of securities and/or Financial Instruments and Money Market Instruments, or (ii) represent interests in a trust or similar entity that holds a specified non-U.S. currency deposited with the trust or similar entity when aggregated in some specified minimum number may be surrendered to the trust by the beneficial owner to receive the specified non-U.S. currency and pays the beneficial owner interest and other distributions on the deposited non-U.S. currency, if any, declared and paid by the trust; or (iii) represent commodity pool interests principally engaged, directly or indirectly, in holding and/or managing portfolios or baskets of securities, commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or non-U.S. currency (“Commodity Pool Units”), or (iv) represent interests in the SPDR Gold Trust, or (v) represent interests in the iShares COMEX Gold Trust, or (vi) represent interests in the iShares Silver Trust, (vii) represents an interest in a registered investment company (“Investment Company”) organized as an open-end management investment company or similar entity, that invests in a portfolio of securities selected by the Investment Company’s investment adviser consistent with the Investment Company’s investment objectives and policies, which is issued in a specified aggregate minimum number in return for a deposit of a specified portfolio of securities and/or a cash amount with a value equal to the next determined net asset value (“NAV”), and when aggregated in the same specified minimum number, may be redeemed at a holder’s request, which holder will be paid a specified portfolio of securities and/or cash with a value equal to the next determined NAV (“Managed Fund Share”), or, (viii) represents interests in the ETFs Silver Trust or ETFs Gold Trust, or, (ix) represents interests in the ETFs Palladium Trust or ETFs Platinum Trust.

¹⁴ Securities deemed appropriate for options trading shall include shares or other securities (“Equity Index-Linked Securities”, “Commodity-Linked Securities”, “Currency-Linked Securities”, “Fixed Income Index-Linked Securities”, “Futures-Linked Securities”, and “Multifactor Index-Linked Securities”, collectively known as “Index-Linked Securities”), as defined in Rule 5.2–E(j)(6), that are principally traded on a national securities exchange and an “NMS stock” (as defined in Rule 600 of Regulation NMS under the Securities and Exchange Act of 1934), and represent ownership of a security that provides for the payment at maturity, as described below; Equity Index-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of an underlying index or indexes of equity securities

expiration date more than 21 days from the listing date. This proposal does not amend the monthly or quarterly listing rules, nor does it amend the \$1 Strike Price Interval Program, the \$0.50 Strike Price Program, the \$2.50 Strike Price Program, or the \$5 Strike Program.

Short Term Option Series Program

After an option class has been approved for listing and trading on the Exchange,¹⁵ Rule 6.4–O, Commentary

(“Equity Reference Asset”); Commodity-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of one or more physical commodities or commodity futures, options on commodities, or other commodity derivatives or Commodity-Based Trust Shares or a basket or index of any of the foregoing (“Commodity Reference Asset”); Currency-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of one or more currencies, or options on currencies or currency futures or other currency derivatives or Currency Trust Shares (as defined in Rule 8.202–E(c)) or a basket or index of any of the foregoing (“Currency Reference Asset”); Fixed Income Index-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of one or more notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities (“Treasury Securities”), government-sponsored entity securities (“GSE Securities”), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof or a basket or index of any of the foregoing (“Fixed Income Reference Asset”); Futures-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of an index or indexes of futures contracts or options or derivatives on futures contracts (a “Futures Reference Asset”); and Multifactor Index-Linked Securities are securities that provide for the payment at maturity of a cash amount based on the performance or the leveraged (multiple or inverse) performance of any combination of two or more Equity Reference Assets, Commodity Reference Assets, Currency Reference Assets, Fixed Income Reference Assets, or Futures Reference Assets (a “Multifactor Reference Asset”).

¹⁵ The Exchange may have no more than a total of five Short Term Option Expiration Dates, not including any Monday or Wednesday SPY Expirations as provided in paragraph (g). If the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on the Friday that the options are set to expire, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday. See Rule 6.4–O, Commentary .07. The Exchange may open for trading on any Friday or Monday that is a business day series of options on the SPDR S&P 500 ETF Trust (“SPY”) to expire on any Monday of the month that is a business day and is not a Monday on which Quarterly Options Series expire (“Monday SPY Expirations”), provided that any Friday on which the Exchange opens for trading a Monday SPY Expiration is one business week and one business day prior to expiration. The Exchange may also open for trading on any Tuesday or Wednesday that is a business day series of SPY

.07 permits the Exchange to open for trading on any Thursday or Friday that is a business day (“Short Term Option Opening Date”) series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays on which monthly options series or Quarterly Options Series expire (“Short Term Option Expiration Dates”). The Exchange may select up to fifty currently listed option classes on which Short Term Option Series may be opened on any Short Term Option Opening Date. In addition to the fifty option class restriction, the Exchange may also list Short Term Option Series on any option classes that are selected by other securities exchanges that employ a similar program under their respective rules. For each option class eligible for participation in the Short Term Option Series Program, the Exchange may open up to 30 Short Term Option Series for each expiration date in that class. The Exchange may also open Short Term Option Series that are opened by other securities exchanges in option classes selected by such exchanges under their respective short term option rules.¹⁶ Pursuant to Rule 6.4–O Commentary .07(c), the Exchange may open up to 30 initial series for each option class that participates in the Short Term Option Series Program and, pursuant to Rule 6.4–O Commentary .07(d), if the Exchange opens less than 30 Short Term Option Series for a Short Term Option Expiration Date, additional series may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. Rule 6.4–O, Commentary .07(e) provides that, if the class does not trade in \$1 strike price intervals, the strike price interval for Short Term Option Series may be: (i)

options to expire on any Wednesday of the month that is a business day and is not a Wednesday on which Quarterly Options Series expire (“Wednesday SPY Expirations”). The Exchange may list up to five consecutive Monday SPY Expirations and up to five consecutive Wednesday SPY Expirations at one time; the Exchange may have no more than a total of five Monday SPY Expirations and no more than a total of five Wednesday SPY Expirations. Monday and Wednesday SPY Expirations will be subject to the provisions of this Rule. See Rule 6.4–O, Commentary .07(f). With the exception of Monday and Wednesday SPY Expirations, no Short Term Option Series may expire in the same week in which monthly option series on the same class expire or, in the case of Quarterly Options Series, on an expiration that coincides with an expiration of Quarterly Options Series on the same class. See Rule 6.4–O, Commentary .07.

¹⁶ See Rule 6.4–O, Commentary .07(a).

\$0.50 or greater where the strike price is less than \$75; (ii) \$1.00 or greater where the strike price is between \$75 and \$150; or (iii) \$2.50 or greater for strike prices greater than \$150.¹⁷

The Exchange notes that listings in the weekly program comprise a significant part of the standard listing in options markets and that the industry has observed a notable increase over approximately the last five years in compound annual growth rate (“CAGR”) of weekly strikes as compared to CAGR for standard third-Friday expirations.¹⁸

Proposal

The Exchange proposes to widen the intervals between strikes in order to limit the number of strikes listed for equity options (excluding options on

ETFs and Index-Linked Securities) listed as part of the Short Term Option Series Program that have an expiration date more than 21 days from the listing date, by adopting proposed Rule 6.4–O, Commentary .07(f). The Exchange notes that this proposal is substantively identical to the strike interval proposal recently submitted by Nasdaq BX, Inc. (“BX”) and approved by the Securities and Exchange Commission (“Commission”).¹⁹

The proposal widens intervals between strikes for expiration dates of equity option series (excluding options on ETFs and Index-Linked Securities) beyond 21 days utilizing the three-tiered table in proposed Rule 6.4–O, Commentary .07(f) (presented below) which considers both the Share Price and Average Daily Volume for the

option series. The table indicates the applicable strike intervals and supersedes Rule 6.4–O, Commentary .07(d), which currently permits 10 additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. As a result of the proposal Rule 6.4–O, Commentary .07(d) would not permit an additional series of an equity option to have an expiration date more than 21 days from the listing date to be opened for trading on the Exchange despite the noted circumstances in paragraph (d) when such additional series may otherwise be added.

Tier	Average daily volume	Share price				
		Less than \$25	\$25 to less than \$75	\$75 to less than \$150	\$150 to less than \$500	\$500 or greater
1	Greater than 5,000	\$0.50	\$1.00	\$1.00	\$5.00	\$5.00
2	Greater than 1,000 to 5,000	1.00	1.00	1.00	5.00	10.00
3	0 to 1,000	2.50	5.00	5.00	5.00	10.00

Proposed Rule 6.4–O, Commentary .07(f)(1) provides that the Share Price is the closing price on the primary market on the last day of the calendar quarter. This value is used to derive the column from which to apply strike intervals throughout the next calendar quarter. Also, proposed Rule 6.4–O, Commentary .07(f)(1) provides that in the event of a corporate action, the Share Price of the surviving company is utilized.²⁰ Proposed Rule 6.4–O, Commentary .07(f)(2) provides that the Average Daily Volume is the total number of option contracts traded in a given security for the applicable calendar quarter divided by the number of trading days in the applicable calendar quarter. Beginning on the second trading day in the first month of each calendar quarter, the Average Daily Volume is calculated by utilizing data from the prior calendar quarter based on

Customer-cleared volume at OCC. For options listed on the first trading day of a given calendar quarter, the Average Daily Volume is calculated using the calendar quarter prior to the last trading calendar quarter.²¹ Pursuant to current Rule 6.4–O, Commentary .07, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday.

By way of example, if the Share Price for a symbol was \$142 at the end of a calendar quarter, with an Average Daily Volume greater than 5,000, thereby, requiring strike intervals to be listed \$1.00 apart, that strike interval would apply for the calendar quarter, regardless of whether the Share Price changed to \$150 or greater during that calendar quarter.²² The proposed table

within Rule 6.4–O, Commentary .07(f) takes into account the notional value of a security, as well as Average Daily Volume in the underlying stock, in order to widen the intervals between strikes and thereby limit the number of strikes listed for equity options (excluding options on ETFs and Index-Linked Securities) in the Short Term Option Series listing program. The Exchange will utilize OCC Customer-cleared volume, as customer volume is an appropriate proxy for demand. The OCC Customer-cleared volume represents the majority of options volume executed on the Exchange, which, in turn, reflects the demand in the marketplace. The options series listed on the Exchange are intended to meet customer demand by offering an appropriate number of strikes. Non-Customer cleared OCC volume generally represents the supply side.

¹⁷ Additionally, Rule 6.4–O, Commentary .07 (e) provides that the interval between strike prices on Short Term Option Series shall be the same as the strike prices for series in that same option class that expire in accordance with the normal monthly expiration cycle. During the expiration week of an option class that is selected for the Short Term Option Series Program pursuant to this rule (“Short Term Option”), the strike price intervals for the related non-Short Term Option (“Related non-Short Term Option”) shall be the same as the strike price intervals for the Short Term Option.

¹⁸ See Securities Exchange Act Release No. 91125 (February 12, 2021), 86 FR 10375 (February 19, 2021) (SR–BX–2020–032) (“BX Strike Interval Approval Order”); and SR–2020–BX–032 as

amended by Amendment No. 1 (February 10, 2021) available at: <https://www.sec.gov/comments/sr-bx-2020-032/srbx2020032-8359799-229182.pdf> (“BX proposal”); see also BX Options Strike Proliferation Proposal (February 25, 2021) available at: <https://www.nasdaq.com/solutions/bx-options-strike-proliferation-proposal>.

¹⁹ See BX Strike Interval Approval Order, *id.*

²⁰ The Exchange notes that corporate actions resulting in change ownership would result in a surviving company, such as a merger of two publicly listed companies, and the Share Price of the surviving company would be used to determine strike intervals pursuant to the proposed table. Corporate actions that do not result in a change of

ownership, such as stock-splits or distribution of special cash dividends, would not result in a “surviving company,” therefore would not impact which Share Price to apply pursuant to the proposed Rule.

²¹ For example, options listed as of April 1, 2021 would be calculated on April 2, 2021 using the Average Daily Volume from October 1, 2020 to December 31, 2020.

²² The Exchange notes that any strike intervals imposed by the Exchange's Rules will continue to apply. In this example, the strikes would be in \$1 intervals up to (but not including) \$150, which is the upper limit imposed by Rule 6.4–O, Commentary .07(e).

The proposal is intended to remove repetitive and unnecessary strike listings across the weekly expiries. Specifically, the proposal seeks to reduce the number of strikes listed in the furthest weeklies, which generally have wider markets and therefore lower market quality.²³ The proposed strike intervals are intended to widen permissible strike intervals in multiply listed equity options (excluding options on ETFs and Index-Linked Securities) where there is less volume as measured by the Average Daily Volume tiers. Therefore, the lower the Average Daily Volume, the greater the proposed spread between strike intervals. Options classes with higher volume contain the most liquid symbols and strikes, which the Exchange believes makes the finer proposed spread between strike intervals for those symbols appropriate. Additionally, lower-priced shares have finer strike intervals than higher-priced shares when comparing the proposed spread between strike intervals. Today, weeklies are available on 16% of underlying products. The proposal limits the density of strikes listed in series of options, without reducing the classes of options available for trading on the Exchange. Short Term Option Series with an expiration date greater than 21 days from the listing date currently equate to 7.5% of the total number of strikes in the options market, which equals 81,000 strikes.²⁴ The Exchange expects this proposal to result in the limitation of approximately 20,000 strikes within the Short Term Option Series, which is approximately 2% of the total strikes in the options markets.²⁵ The Exchange understands there has been an inconsistency of demand for series of options beyond 21 calendar days.²⁶ The proposal takes into account customer demand for certain options classes, by considering both the Share Price and the Average Daily Volume, in order to remove certain

strike intervals where there exist clusters of strikes whose characteristics closely resemble one another and, therefore, do not serve different trading needs,²⁷ rendering these strikes less useful. The Exchange also notes that the proposal focuses on strikes in multiply listed equity options, and excludes ETFs and Index-Linked Securities, as the majority of strikes reside within equity options.

Additionally, proposed Rule 6.4–O, Commentary .07(f)(3) provides that options that are newly eligible for listing pursuant to Rule 5.3–O and designated to participate in the Short Term Option Series program pursuant to Rule 6.4–O, Commentary .07(f) will not be subject to subparagraph (f) (as proposed) until after the end of the first full calendar quarter following the date the option class was first listed for trading on any options market.²⁸ As proposed, the Exchange is permitted to list options on newly eligible listings, without having to apply the wider strike intervals, until the end of the first full calendar quarter after such options were listed. The proposal thereby permits the Exchange to add strikes to meet customer demand in a newly listed options class. A newly eligible option class may fluctuate in price after its initial listing; such volatility reflects a natural uncertainty about the security. By deferring the application of the proposed wider strike intervals until after the end of the first full calendar quarter, additional information on the underlying security will be available to market participants and public investors, as the price of the underlying has an opportunity to settle based on the price discovery that has occurred in the primary market during this deferment period. Also, the Exchange has the ability to list as many strikes as are permissible for the Short Term Option Series once the expiry is no more than 21 days. Short Term Option Series that have an expiration date no more than 21 days from the listing date are not subject to the proposed strike intervals, which allows the Exchange to list additional, and potentially narrower, strikes in the event of market volatility or other market events. These metrics are intended to align expectations for determining which strike intervals will

be utilized. Finally, proposed Rule 6.4–O, Commentary .07(f)(4) provides that, notwithstanding the strike intervals imposed in proposed subparagraph (f), the proposal does not amend the range of strikes that may be listed pursuant to subparagraph (e).

While the current listing rules permit the Exchange to list a number of weekly strikes on its market, in an effort to encourage Market Makers to deploy capital more efficiently, as well as improve displayed market quality, the proposal aims to reduce the density of strikes listed in later weeks by widening the intervals between strikes listed for equity options (excluding options on ETFs and Index-Linked Securities) which have an expiration date more than 21 days from the listing date. The Exchange requires Lead Market Makers (“LMMs”) and Market Makers to quote during a certain amount of time in the trading day and in a certain percentage of series in their assigned options classes to maintain liquidity in the market.²⁹ With an increasing number of strikes being listed across options exchanges, Market Makers must expend their capital to ensure that they have the appropriate infrastructure to meet their quoting obligations on all options markets in which they are assigned in option classes. The Exchange believes that by widening the intervals between strikes listed for equity options (excluding options on ETFs and Index-Linked Securities), thus reducing the number of strikes listed on the Exchange, the proposal will likewise reduce the number of weekly strikes in which LMMs and Market Makers are required to quote and, as a result, allow LMMs and Market Makers to expend their capital in the options market in a more efficient manner. Due to this increased efficiency, the Exchange believes that the proposal may improve overall market quality on the Exchange by widening the intervals between strikes in multiply listed equity options (excluding options on ETFs and Index-Linked Securities) that have an expiration date more than 21 days from the listing date. The proposal is intended to balance the goal of limiting the number of listed strikes with the needs of market participants. The Exchange believes that the various permissible strike intervals will continue to offer market participants the ability to select the appropriate strikes to meet their investment objectives.

Implementation

The Exchange will announce the implementation date of the proposed

²³ See BX proposal, *supra* note 18, which presents tables that focus on data for 10 of the most and least actively traded symbols and demonstrate average spreads in weekly options during the month of August 2020.

²⁴ The Exchange notes that this proposal is an initial attempt at reducing strikes and anticipates filing additional proposals to continue reducing strikes. The percentage of underlying products and percentage of and total number of strikes, are approximations and may vary slightly at the time of this filing. The Exchange intends to decrease the overall number of strikes listed on the NYSE Group options exchanges in a methodical fashion, so that it may monitor progress and feedback from its OTP Holders. The Exchange also notes that its affiliated options exchange, NYSE American Options LLC plans to submit an identical proposal.

²⁵ From information drawn from time period between January 2020 and May 2020. See BX proposal, *supra* note 18.

²⁶ See BX proposal, *supra* note 18.

²⁷ For example, two strikes that are densely clustered may have the same risk properties and may also be the same percentage out-of-the-money.

²⁸ For example, if an options class became newly eligible for listing pursuant to Rule 5.3–O on March 1, 2021 (and was actually listed for trading that day), the first full quarterly lookback would be available on July 1, 2021. This option would become subject to the proposed strike intervals on July 2, 2021.

²⁹ See Rule 6.37A–O.

rule change by Trader Update to be published no later than 30 days following the operative date of the proposed rule. The implementation date will be no later than 30 days following the issuance of the Trader Update. The Exchange will issue a Trader Update³⁰ to its OTP Holders whenever the Exchange is the first exchange to list a class as eligible for Short Term Option Series pursuant to Rule 6.4–O, Commentary .07.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.³¹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³² requirements that the rules of an 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, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposal seeks to widen the permissible intervals between strikes listed for equity options (excluding options on ETFs and Index-Linked Securities) in order to limit the number of strikes listed in the Short Term Option Series program that have an expiration date more than 21 days. The proposal removes impediments to and perfects the mechanism of a free and open market and a national market system by encouraging Market Makers to deploy capital more efficiently,

which may improve market quality overall on the Exchange, by widening the intervals between strikes when applying the strike interval table to multiply listed equity options (excluding options on ETFs and Index-Linked Securities) that have an expiration date more than 21 days from the listing date. As described above, the Exchange requires LMMs and Market Makers to quote during a certain amount of time in the trading day and in a certain percentage of series in their assigned options classes to maintain liquidity in the market.³⁴ With an increasing number of strikes due, in part, to tighter intervals being listed across options exchanges, Market Makers must expend their capital to ensure that they have the appropriate infrastructure to meet their quoting obligations on all options markets in which they are assigned in options classes. The Exchange believes that this proposal will widen the intervals between strikes listed on the Exchange, thereby reducing the number of weekly options listed on its market in later weeks in which Market Makers are required to quote and, in turn, allowing DPMs and Market Makers to expend their capital in the options market in a more efficient manner.

The Exchange believes that limiting the permissible strikes for multiply listed equity options (excluding options on ETFs and Index-Linked Securities) that have an expiration date more than 21 days from the listing date will not significantly disrupt the market, as the majority of the volume traded in weekly options exists in options series which have an expiration date of 21 days or less. The proposal will limit the number of strikes listed in series of options without reducing the number of classes of options available for trading on the Exchange. The proposal allows the Exchange to determine the weekly strike intervals for multiply listed equity Short Term Option Series listed in the later weeks by taking into account customer demand for certain options classes by considering both the Share Price and the Average Daily Volume in the underlying security. The Exchange utilizes OCC Customer-cleared volume, as customer volume is an appropriate proxy for demand. Whereas non-Customer cleared OCC volume generally represents the supply side, the Exchange believes OCC Customer-cleared volume represents the majority of options volume executed on the Exchange, which, in turn, reflects the demands in the marketplace and is therefore intended to assist the Exchange in meeting customer demand

by offering an appropriate number of strikes.

The proposal is intended to remove certain strikes where there exist clusters of strikes whose characteristics closely resemble one another and, therefore, do not serve different trading needs, which currently results in less useful strikes. As such, the proposal protects investors and the general public by removing unnecessary choices for an options series, which the Exchange believes may improve market quality. The proposal seeks to reduce the number of strikes in the furthest weeklies, which generally have wider markets, and, therefore, lower market quality. The implementation of the Strike Interval table is intended to allow for greater spreads between strike intervals in multiply listed equity options where there is less volume as measured by the Average Daily Volume tiers. Therefore, the lower the Average Daily Volume, the wider the proposed spread between strike intervals, and the higher the Average Daily Volume (*i.e.*, the options classes that contain the most liquid symbols and strikes), the narrower the proposed spread between strike intervals. Additionally, the proposed strike intervals are finer for lower-priced shares than higher-priced shares.³⁵ As a result, the Exchange believes that, by limiting the permissible strikes for multiply listed equity options (excluding options on ETFs and Index-Linked Securities) that have an expiration date more than 21 days from the listing date pursuant to the proposed Strike Interval table, the proposal may improve overall market quality on the Exchange, which serves to protect investors and the general public.

Further, utilizing the second trading day of a calendar quarter allows the Exchange to accumulate data regarding OCC Customer-cleared volume from the entire prior calendar quarter and allows the calculation of Average Daily Volume to account for trades executed on the last day of the previous calendar quarter, which will have settled by the second trading day.³⁶ The Exchange believes that applying the previous calendar quarter for the calculation is appropriate to reduce the impact of unusual trading activity as a result of unique market events, such as a corporate action (*i.e.*, it may result in a more reliable measure of Average Daily Volume than a shorter period).

³⁰ When the Exchange is the first exchange to list an option class Rule 6.4–O, Commentary .07 the Exchange shall provide a Trader Notice OTP Holders regarding the Short Term Option Series to be listed. Such notice will include for each eligible option class: The closing price of the underlying, the Average Daily Volume of the option class; and the eligible strike category (per the proposed table) in which the eligible option class falls under as a result of the closing price and the Average Daily Volume.

³¹ 15 U.S.C. 78f(b).

³² 15 U.S.C. 78f(b)(5).

³³ *Id.*

³⁴ See *supra* note 30.

³⁵ The Exchange notes that it has discussed the proposed strike intervals with various OTP Holders.

³⁶ Options contracts settle one business day after trade date. Strike listing determinations are made the day prior to the start of trading in each series.

As stated, the proposal is substantively identical to the strike interval proposal recently submitted by BX and approved by the Commission.³⁷ The Exchange believes that varied strike intervals will continue to offer market participants the ability to select the appropriate strike interval to meet that market participants' investment objectives.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as the proposed rule change limits the number of Short Term Option Series strikes available for quoting and trading on the Exchange for all market participants. Therefore, all market participants will equally be able to transact in options series in the strikes listed for trading on the Exchange. The proposal is intended to reduce the number of strikes for weekly options listed in later weeks without reducing the number of classes of options available for trading on the Exchange while also continuing to offer an appropriate number of strikes the Exchange believes will meet market participants' investment objectives.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as it only impacts the permissible strike intervals for certain options series listed on the Exchange. Additionally, another options exchange has recently implemented a substantively identical rule for listing Short Term Option Series strike intervals on its exchange, approved by the Commission.³⁸ The proposal is a competitive response that will permit the Exchange to list the same series in multiply listed options as another options exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii)³⁹ of the Act and Rule 19b-4(f)(6) thereunder.⁴⁰ Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act and subparagraph (f)(6) of Rule 19b-4 thereunder.⁴¹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act⁴² normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)⁴³ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may implement the proposed rule change at the same time that all other options exchanges implement their respective rule changes. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change is substantively identical to rules adopted by each other options exchange, and therefore the Exchange's proposal does not raise any new or novel issues. Waiver of the operative delay will allow the Exchange to implement its new rule on the same timeline as the other options exchanges, and such coordinated implementation will reduce potential investor confusion and facilitate a harmonized approach to strike listings for options within the

Short Term Option Series program that have an expiration date more than 21 days from the listing date. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.⁴⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2021-55 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-NYSEArca-2021-55. 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

³⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴⁰ 17 CFR 240.19b-4(f)(6).

⁴¹ In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁴² 17 CFR 240.19b-4(f)(6).

⁴³ 17 CFR 240.19b-4(f)(6)(iii).

⁴⁴ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³⁷ See BX Strike Interval Approval Order, *supra* note 18.

³⁸ See BX Strike Interval Approval Order, *supra* note 18.

printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2021-55, and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁵

J. Matthew DeLesDernier,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-92343; File No. SR-NYSE-2021-39]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

July 7, 2021.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 ("Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on June 30, 2021, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to modify the requirements to qualify for Supplemental Liquidity Provider ("SLP") Tier 5. The Exchange proposes to implement the rule change

on July 1, 2021. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its to modify the requirements to qualify for SLP Tier 5.

The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for member organizations to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the rule change on July 1, 2021.

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."⁴

As the Commission itself has recognized, the market for trading services in NMS stocks has become

"more fragmented and competitive."⁵ Indeed, equity trading is currently dispersed across 16 exchanges,⁶ 31 alternative trading systems,⁷ and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 18% of the market.⁸ Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's share of executed volume of equity trades in Tapes A, B and C securities is less than 14%.⁹

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange, member organizations can choose from any one of the numerous currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange [sic].

Proposed Rule Change

In response to the competitive environment described above, the Exchange has established incentives for its member organizations who submit orders that provide liquidity on the Exchange. The proposed fee change is designed to attract additional order flow to the Exchange by incentivizing member organizations to submit additional displayed liquidity to the Exchange.

Proposed Changes to SLP Tier 5

Under current SLP Tier 5, an SLP adding liquidity in securities with a per share price of \$1.00 or more with orders, other than Mid-Point Liquidity ("MPL")

⁵ See Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7-05-18) (Transaction Fee Pilot for NMS Stocks Final Rule) ("Transaction Fee Pilot").

⁶ See Cboe Global Markets, U.S. Equities Market Volume Summary, available at http://markets.cboe.com/us/equities/market_share/. See generally <https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html>.

⁷ See FINRA ATS Transparency Data, available at <https://otctransparency.finra.org/otctransparency/AtsIssueData>. Although 54 alternative trading systems were registered with the Commission as of July 29, 2019, only 31 are currently trading. A list of alternative trading systems registered with the Commission is available at <https://www.sec.gov/foia/docs/atlist.htm>.

⁸ See Cboe Global Markets U.S. Equities Market Volume Summary, available at http://markets.cboe.com/us/equities/market_share/.

⁹ See *id.*

⁴⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7-10-04) (Final Rule) ("Regulation NMS").

orders, is eligible for a per share credit of \$0.0031 (or \$0.0012 if a Non-Displayed Reserve Order) if the SLP:

(1) Meets the 10% average or more quoting requirement in an assigned security pursuant to Rule 107B;

(2) adds liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) of an average daily volume ("ADV") of more than 0.65% of Tape A consolidated ADV ("CADV")¹⁰ (for SLPs that are also DMMs and subject to Rule 107B(i)(2)(A), more than 0.65% after a discount of the percentage for the prior quarter of Tape A CADV in DMM assigned securities as of the last business day of the prior month);

(3) has Adding ADV,¹¹ including non-SLP Adding ADV but excluding any liquidity added by a DMM, that is at least 0.85% of Tape A CADV; and

(4) executes an ADV, including non-SLP Adding ADV but excluding any liquidity added by a DMM, of at least 250,000 shares in Retail Price Improvements Orders.

The Exchange proposes to lower the Adding ADV requirements to qualify for the SLP Tier 5. Specifically, the Exchange proposes that a SLP add liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) of an ADV of more than 0.60% of Tape A CADV. For SLPs that are also DMMs and subject to Rule 107B(i)(2)(A), the requirement would be more than 0.60% after a discount of the percentage for the prior quarter of Tape A CADV in DMM assigned securities as of the last business day of the prior month. In addition, the Exchange would require an Adding ADV, including non-SLP Adding ADV but excluding any liquidity added by a DMM, that is at least 0.80% of Tape A CADV.

The remaining requirements for qualifying for SLP Tier 5 and the existing credits would remain unchanged.

The Exchange believes that lowering the ADV requirements to qualify for SLP Tier 5 as proposed above will allow greater numbers of SLPs to potentially qualify for the tier, and will incentivize more SLPs to route their liquidity-providing order flow to the Exchange in order to qualify for the tier. This in turn would support the quality of price

discovery on the Exchange and provide additional price improvement opportunities for incoming orders.

As noted above, the Exchange operates in a competitive environment, particularly as relates to attracting non-marketable orders, which add liquidity to the Exchange. The Exchange believes that the lower requirements will provide greater incentives for SLPs to add more liquidity to the Exchange. The Exchange does not know how much order flow SLPs choose to route to other exchanges or to off-exchange venues. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional SLPs could qualify for the tier under the revised qualification criteria if they choose to direct order flow to, and increase quoting on, the Exchange. However, without having a view of SLP's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any additional SLPs directing orders to the Exchange in order to qualify for the SLP Tier 5 rates.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹² in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹³ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to

investors and listed companies."¹⁴ While Regulation NMS has enhanced competition, it has also fostered a "fragmented" market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that "such competition can lead to the fragmentation of order flow in that stock."¹⁵

Given the current competitive environment, the Exchange believes that the proposed revisions to the requirements for SLPs to qualify for SLP Tier 5 represents a reasonable attempt to attract additional order flow to the Exchange. Specifically, the Exchange believes that the proposed revisions are reasonable because they would provide further incentives for member organizations that are SLPs to route additional liquidity-providing orders to a public exchange to reach the proposed Adding ADV requirements, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations. All member organizations would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

As noted above, the Exchange operates in a competitive environment, particularly as relates to attracting non-marketable orders, which add liquidity to the Exchange. The Exchange believes that the lower requirements will provide greater incentives for SLPs to add more liquidity to the Exchange. The Exchange does not know how much order flow SLPs choose to route to other exchanges or to off-exchange venues. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional SLPs could qualify for the tier under the revised qualification criteria if they choose to direct order flow to, and increase quoting on, the Exchange. However, without having a view of SLP's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any additional SLPs directing orders to the Exchange in order to qualify for the SLP Tier 5 credits.

¹⁰ The terms "ADV" and "CADV" are defined in footnote * of the Price List.

¹¹ Footnote 2 to the Price List defines "Adding ADV" as ADV that adds liquidity to the Exchange during the billing month.

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(4) & (5).

¹⁴ See Regulation NMS, *supra* note 4, at 37499.

¹⁵ See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7-02-10) (Concept Release on Equity Market Structure).

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposed rule change equitably allocates its fees among its market participants. The proposed change would continue to encourage member organizations that are SLPs to submit additional liquidity to the Exchange and execute orders on the Exchange, thereby contributing to robust levels of liquidity, to the benefit of all market participants.

The Exchange believes that modifying the requirements to qualify for SLP Tier 5 would encourage the submission of additional liquidity to the Exchange, thereby providing customers with a higher quality venue for price discovery, liquidity, competitive quotes and price improvement. The proposed change will thereby encourage the submission of additional liquidity to a national securities exchange, thus promoting price discovery and transparency and enhancing order execution opportunities for member organizations from the substantial amounts of liquidity present on the Exchange. All member organizations would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. Specifically, the Exchange believes that the proposal constitutes an equitable allocation of fees because all similarly situated SLPs would be eligible for the same credits if they meet the revised requirements for the tier. As to those SLPs that do not presently qualify for the adding liquidity credits, the proposal will not adversely impact their existing pricing or their ability to qualify for other credits provided by the Exchange.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

The proposed changes to the SLP Tier 5 are not unfairly discriminatory because the lower ADV requirements to achieve the fee would be applied to all similarly situated member organizations and other market participants, who would all be subject to the same modified requirements to qualify for the tier and the same credits on an equal basis. For the same reason, the proposal

neither targets nor will it have a disparate impact on any particular category of market participant. Accordingly, no member organization already operating on the Exchange would be disadvantaged by this allocation of fees. Further, the Exchange believes the proposal would incentivize member organizations that are SLPs to send more orders to the Exchange to qualify for higher credits.

The Exchange believes that the proposed changes would not permit unfair discrimination among SLPs because the tiered rates are available equally to all SLPs. As described above, in today's competitive marketplace, order flow providers have a choice of where to direct liquidity-providing order flow, and the Exchange believes there are additional SLPs that could qualify if they chose to direct their order flow to the Exchange. Finally, the submission of orders to the Exchange is optional for member organizations in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹⁶ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity and order flow to a public exchange, thereby enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."¹⁷

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. As described above, the Exchange believes that the proposed change would provide additional incentives for

market participants to route liquidity-providing and liquidity-removing orders to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages member organizations to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants on the Exchange. The current and proposed credits would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁸ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁹ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if

¹⁶ 15 U.S.C. 78f(b)(8).

¹⁷ Regulation NMS, 70 FR at 37498-99.

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f)(2).

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) ²⁰ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSE-2021-39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSE-2021-39. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit

personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSE-2021-39 and should be submitted on or before August 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-14798 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34325; File No. 812-15195]

Commonwealth Credit Partners BDC I, Inc., et al.

July 7, 2021.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the "Act") and rule 17d-1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d-1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies ("BDCs") and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment funds and accounts.

APPLICANTS: Commonwealth Credit Partners BDC I, Inc. (the "Existing Regulated Fund"), Commonwealth Credit Advisors LLC ("CCA"), Comvest Capital Advisors, LLC ("Comvest Capital"), Comvest Credit Advisors, LLC ("Comvest Credit"), Comvest SG Advisors, LLC ("Comvest SG"), and each of the Existing Affiliated Funds set forth on Schedule A of the application.

FILING DATES: The application was filed on January 26, 2021, and amended on April 15, 2021, and on July 1, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at Secretarys-Office@sec.gov and serving applicants

with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on July 30, 2021, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at Secretarys-Office@sec.gov.

ADDRESSES: The Commission: Secretarys-Office@sec.gov. Applicants: m.altschuler@comvest.com; richard.horowitz@dechert.com.

FOR FURTHER INFORMATION CONTACT: Asen Parachkevov, Senior Counsel, at (202) 551-6908 or Lisa Reid Ragen, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

Introduction

1. The applicants request an order of the Commission under sections 17(d) and 57(i) and rule 17d-1 thereunder (the "Order") to permit, subject to the terms and conditions set forth in the application (the "Conditions"), a Regulated Fund¹ and one or more other Regulated Funds and/or one or more Affiliated Funds² to enter into Co-

¹ "Regulated Funds" means the Existing Regulated Fund, the Future Regulated Funds and the BDC Downstream Funds (defined below). "Future Regulated Fund" means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a BDC, (b) whose investment adviser (and sub-adviser(s), if any) are an Adviser, and (c) that intends to participate in the Co-investment Program.

"Adviser" means CCA and any future investment adviser that (i) controls, is controlled by, or is under common control with CCA, (ii) (a) is registered as an investment adviser under the Investment Advisers Act of 1940 ("Advisers Act") or (b) is a relying adviser of an investment adviser that is registered under the Advisers Act, and that controls, is controlled by, or is under common control with, CCA, and (iii) is not a Regulated Fund or a subsidiary of a Regulated Fund.

² "Affiliated Fund" means the Existing Affiliated Fund, any Comvest Proprietary Account (as defined below) and any entity (a) whose investment adviser (and sub-adviser(s), if any) are Advisers, (b) that either (i) would be an investment company but for

²⁰ 15 U.S.C. 78s(b)(2)(B).

²¹ 17 CFR 200.30-3(a)(12).

Investment Transactions with each other. “Co-Investment Transaction” means any transaction in which a Regulated Fund (or its Wholly-Owned Investment Sub (as defined below)) participated together with one or more Affiliated Funds and/or one or more other Regulated Funds in reliance on the Order. “Potential Co-Investment Transaction” means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.³

Applicants

2. The Existing Regulated Fund is an externally-managed, non-diversified, closed-end management investment company incorporated in Delaware that has elected to be regulated as a BDC under the Act.⁴ The Board⁵ of the Existing Regulated Fund currently consist of four members, three of whom are Independent Directors.⁶

section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act or (ii) relies on rule 3a-7 under the Act, (c) that is not a BDC Downstream Fund, and (d) that intends to participate in the Co-Investment Program.

“BDC Downstream Fund” means, with respect to any Regulated Fund that is a business development company (“BDC”), an entity (i) that the BDC directly or indirectly controls, (ii) that is not controlled by any person other than the BDC (except a person that indirectly controls the entity solely because it controls the BDC), (iii) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act, (iv) whose investment adviser (and sub-adviser(s), if any) are an Adviser, (v) that is not a Wholly-Owned Investment Sub and (vi) that intends to participate in the Co-Investment Program (defined below).

³ All existing entities that currently intend to rely on the Order have been named as applicants and any existing or future entities that may rely on the Order in the future will comply with its terms and Conditions set forth in the application.

⁴ Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) and makes available significant managerial assistance with respect to the issuers of such securities.

⁵ “Board” means (i) with respect to a Regulated Fund other than a BDC Downstream Fund, the board of directors (or the equivalent) of the Regulated Fund and (ii) with respect to a BDC Downstream Fund, the Independent Party of the BDC Downstream Fund.

“Independent Party” means, with respect to a BDC Downstream Fund, (i) if the BDC Downstream Fund has a board of directors (or the equivalent), the board or (ii) if the BDC Downstream Fund does not have a board of directors (or the equivalent), a transaction committee or advisory committee of the BDC Downstream Fund.

⁶ “Independent Director” means a member of the Board of any relevant entity who is not an “interested person” as defined in section 2(a)(19) of the Act. No Independent Director of a Regulated Fund (including any non-interested member of an Independent Party) will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds.

3. CCA, a limited liability company under the laws of the state of Delaware, is registered with the Commission as an investment adviser under the Advisers Act and will serve as the investment adviser of the Existing Regulated Fund.

4. Comvest Capital is a Delaware limited liability company that serves as the investment adviser to certain Existing Affiliated Funds on behalf of itself and its successors. Comvest Credit is a Delaware limited liability company that serves as the investment adviser to certain Existing Affiliated Funds on behalf of itself and its successors. Comvest SG is a Delaware limited liability company that serves as the investment adviser to certain Existing Affiliated Funds on behalf of itself and its successors.

5. Any Adviser, and any direct or indirect, wholly- or majority-owned subsidiary of an Adviser, may hold various financial assets in a principal capacity (the “Comvest Proprietary Accounts”).

6. Applicants represent that each Existing Affiliated Fund is a separate and distinct legal entity and each would be an investment company but for section 3(c)(7) of the Act or relies on Rule 3a-7 under the Act.

7. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.⁷ Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d-1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the Regulated Fund that owns it and that the Wholly-

Owned Investment Sub’s participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly.

Applicants’ Representations

A. Allocation Process

8. Applicants represent that CCA has established processes for allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably. Further, applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

9. Opportunities for Potential Co-Investment Transactions may arise when investment advisory personnel of an Adviser becomes aware of investment opportunities that may be appropriate for a Regulated Fund and one or more other Regulated Funds and/or one or more Affiliated Funds. If the requested Order is granted, the Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that, when such opportunities arise, the Advisers to the relevant Regulated Funds are promptly notified and receive the same information about the opportunity as any other Advisers considering the opportunity for their clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies⁸ and any Board-Established Criteria⁹ of a Regulated

⁸ “Objectives and Strategies” means (i) with respect to any Regulated Fund other than a BDC Downstream Fund, its investment objectives and strategies, as described in its most current registration statement on Form N-2, other current filings with the Commission under the Securities Act of 1933 (“Securities Act”) or under the Securities Exchange Act of 1934, as amended, and its most current report to stockholders, and (ii) with respect to any BDC Downstream Fund, those investment objectives and strategies described in its disclosure documents (including private placement memoranda and reports to equity holders) and organizational documents (including operating agreements).

⁹ “Board-Established Criteria” means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to the Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund’s Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund’s Adviser will be notified of all Potential Co-

⁷ “Wholly-Owned Investment Sub” means an entity (i) that is wholly-owned by a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 95% or more of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund (and in the case of an SBIC Subsidiary, maintain a license under the Small Business Investment Act of 1958 (“SBA Act”) and issue debentures guaranteed by the Small Business Administration (“SBA”)); (iii) with respect to which such Regulated Fund’s Board has the sole authority to make all determinations with respect to the entity’s participation under the Conditions; and (iv) that (A) would be an investment company but for section 3(c)(1), 3(c)(5)(C), or 3(c)(7) of the Act, or (B) that qualifies as a real estate investment trust within the meaning of section 856 of the Internal Revenue Code because substantially all of its assets would consist of real properties. “SBIC Subsidiary” means a Wholly-Owned Investment Sub that is licensed by the SBA to operate under the SBA Act as a small business investment company.

Fund, the policies and procedures will require that the Adviser to such Regulated Fund receive sufficient information to allow such Adviser's investment committee to make its independent determination and recommendations under the Conditions. The Adviser to each applicable Regulated Fund will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in such Potential Co-Investment Transaction to be appropriate, then it will formulate a recommendation regarding the proposed order amount for the Regulated Fund.

10. Applicants state that, for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, the Adviser's investment committee will approve an investment amount. Prior to the External Submission (as defined below), each proposed order amount may be reviewed and adjusted, in accordance with the applicable Advisers' written allocation policies and procedures, by the applicable Adviser's investment committee.¹⁰ The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its "Internal Order." The Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.¹¹

Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify their approval of any Board-Established Criteria, though applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

¹⁰ The reason for any such adjustment to a proposed order amount will be documented in writing and preserved in the records of each Adviser.

¹¹ "Required Majority" means a required majority, as defined in section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o). In the case of a BDC Downstream Fund with a board of directors (or the equivalent), the members that make up the Required Majority will be determined

11. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the "External Submission"), then each Internal Order will be fulfilled as placed. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders.¹² If, subsequent to such External Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds' or the Affiliated Funds' consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that the Advisers will establish, implement and maintain.¹³

B. Follow-On Investments

12. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments¹⁴ in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

as if the BDC Downstream Fund were a BDC subject to section 57(o). In the case of a BDC Downstream Fund with a transaction committee or advisory committee, the committee members that make up the Required Majority will be determined as if the BDC Downstream Fund were a BDC subject to section 57(o) and as if the committee members were directors of the fund.

¹² The Advisers will maintain records of all proposed order amounts, Internal Orders and External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with the Conditions.

"Eligible Directors" means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund's Board eligible to vote on that Potential Co-Investment Transaction under section 57(o) of the Act (treating any registered investment company or series thereof as a BDC for this purpose).

¹³ The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with Condition 2, 6, 7, 8 or 9, as applicable.

¹⁴ "Follow-On Investment" means an additional investment in the same issuer, including, but not limited to, through the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

13. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.¹⁵ If the Regulated Funds and Affiliated Funds had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds would need to comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be governed by the requirements of Standard Review Follow-Ons.

14. A Regulated Fund would be permitted to invest in Standard Review Follow-Ons either with the approval of the Required Majority under Condition 8(c) or without Board approval under Condition 8(b) if it is (i) a Pro Rata Follow-On Investment¹⁶ or (ii) a Non-Negotiated Follow-On Investment.¹⁷

¹⁵ "Pre-Boarding Investments" are investments in an issuer held by a Regulated Fund as well as one or more Affiliated Funds and/or one or more other Regulated Funds that were acquired prior to participating in any Co-Investment Transaction: (i) In transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); or (ii) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated Fund.

¹⁶ A "Pro Rata Follow-On Investment" is a Follow-On Investment (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investments in the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in the pro rata Follow-On Investments as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund's Eligible Directors in accordance with Condition 8(c).

¹⁷ A "Non-Negotiated Follow-On Investment" is a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Funds and/or one or more other Regulated Funds

Continued

Applicants believe that these Pro Rata and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or the attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board's periodic review in accordance with Condition 10.

C. Dispositions

15. Applicants propose that Dispositions¹⁸ would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in the issuer had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.¹⁹

16. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without Board approval under Condition 6(c) if (i) the Disposition is a

Pro Rata Disposition²⁰ or (ii) the securities are Tradable Securities²¹ and the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

17. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class, registration rights and any other rights, so that none of them receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa. Nevertheless, in all cases, (i) the date on which the commitment of the Affiliated Funds and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

18. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the

"Holders") own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (the "Shares"), then the Holders will vote such Shares as required under the Condition.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d-1 under the Act prohibit participation by a registered investment company and an affiliated person in any "joint enterprise or other joint arrangement or profit-sharing plan," as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d-1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d-1 also applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of rule 17d-1 and section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Affiliated Funds and the Regulated Funds participating in such transactions fall within the category of persons described by rule 17d-1 and/or section 57(b), as modified by rule 57b-1 thereunder, as applicable, vis-à-vis each participating Regulated Fund. Each of the participating Regulated Funds and Affiliated Funds may be deemed to be affiliated persons vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) by reason of common control because (i) an Adviser that is either CCA or an entity that controls, is controlled by, or under common control with CCA will be the investment adviser (and sub-adviser, if any) to each of the Regulated Funds and the Affiliated Funds; (ii) CCA is the Adviser to, and may be deemed to control the Existing Regulated Fund; and an Adviser will be the investment adviser and sub-adviser to, and may be deemed to control, any Future Regulated Fund; (iii) each BDC

(i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters.

"JT No-Action Letters" means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

¹⁸ "Disposition" means the sale, exchange or other disposition of an interest in a security of an issuer.

¹⁹ However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition, and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (i.e., in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition), and the other terms of the investments. This additional review would be required because such findings would not have been required in connection with the prior Enhanced Review Disposition, but they would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

²⁰ A "Pro Rata Disposition" is a Disposition (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

²¹ "Tradable Security" means a security that meets the following criteria at the time of Disposition: (i) It trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) it is not subject to restrictive agreements with the issuer or other security holders; and (iii) it trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

Downstream Fund will be deemed to be controlled by its BDC parent and/or its BDC parent's Adviser; and (iv) the Advisers are under common control. Thus, each Regulated Fund and each Affiliated Fund could be deemed to be a person related to a Regulated Fund, or BDC Downstream Fund, in a manner described by section 57(b) and related to the other Regulated Funds in a manner described by rule 17d-1; and therefore the prohibitions of rule 17d-1 and section 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in Co-Investment Transactions with the Regulated Funds. Further, because the BDC Downstream Funds and Wholly-Owned Investment Subs are controlled by the Regulated Funds, the BDC Downstream Funds and Wholly-Owned Investment Subs are subject to section 57(a)(4) (or section 17(d) in the case of Wholly-Owned Investment Subs controlled by Regulated Funds that are registered under the Act) and thus also subject to the provisions of rule 17d-1. In addition, because the Comvest Proprietary Accounts will be controlled by an Adviser and, therefore, may be under common control with the Existing Regulated Fund, CCA, and any Future Regulated Funds, the Comvest Proprietary Accounts could be deemed to be persons related to the Regulated Funds (or a company controlled by the Regulated Funds) in a manner described by section 17(d) or section 57(b) and also prohibited from participating in the Co-Investment Program.

4. In passing upon applications under rule 17d-1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by rule 17d-1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds being on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their shareholders and do

not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the provisions, policies, and purposes of the Act and would be done in a manner that is not different from, or less advantageous than, that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. Identification and Referral of Potential Co-Investment Transactions.

(a) The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. Board Approvals of Co-Investment Transactions.

(a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c) After making the determinations required in Condition 1(b) above, each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment

Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii) the transaction is consistent with:

(A) the interests of the Regulated Fund's equity holders; and
(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided that the Required Majority shall not be prohibited from reaching the conclusions required by this Condition 2(c)(iii) if:

(A) The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Funds and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other; or

(B) any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to

the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund or any affiliated person of any other Regulated Fund or Affiliated Fund receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv) the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect²² financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B)(z).

3. *Right to Decline.* Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. *General Limitation.* Except for Follow-On Investments made in accordance with Conditions 8 and 9 below,²³ a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.²⁴

²² For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

²³ This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

²⁴ "Related Party" means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate.

"Close Affiliate" means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in section 57(b) (after giving effect to rule 57b-1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except

5. *Same Terms and Conditions.* A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

6. *Standard Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) the Adviser to such Regulated Fund or Affiliated Fund²⁵ will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b) *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund.

(c) *No Board Approval Required.* A Regulated Fund may participate in such

for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D).

"Remote Affiliate" means any person described in section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

²⁵ Any Comvest Proprietary Account that is not advised by an Adviser is itself deemed to be an Adviser for purposes of Conditions 6(a)(i), 7(a)(i), 8(a)(i) and 9(a)(i).

a Disposition without obtaining prior approval of the Required Majority if:

(i) (A) The participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition;²⁶ (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition; or

(ii) each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. *Enhanced Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to

²⁶ In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i) The Disposition complies with Condition 2(c)(i), (ii), (iii)(A), and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d-1, as applicable, and records the basis for the finding in the Board minutes.

(c) *Additional Requirements:* The Disposition may only be completed in reliance on the Order if:

(i) *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and Conditions as those applicable to the Affiliated Funds and any other Regulated Fund;

(ii) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b-1) or rule 17d-1, as applicable;

(iv) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial²⁷ in amount, including immaterial relative to

the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(v) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

8. *Standard Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) *No Board Approval Required.* A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if:

(i) (A) the proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,²⁸ immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as

described in greater detail in the application); or

(ii) it is a Non-Negotiated Follow-On Investment.

(c) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Directors must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) the amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

9. *Enhanced Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the

²⁷ In determining whether a holding is "immaterial" for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

²⁸ To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b-1) or rule 17d-1, as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b-1) or rule 17d-1, as applicable;

(iii) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds,

that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(iv) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. *Board Reporting, Compliance and Annual Re-Approval.*

(a) Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund, and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund

holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors, may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the Conditions.

(b) All information presented to the Regulated Fund's Board pursuant to this Condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

(c) Each Regulated Fund's chief compliance officer, as defined in rule 38a-1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance. In the case of a BDC Downstream Fund that does not have a chief compliance officer, the chief compliance officer of the BDC that controls the BDC Downstream Fund will prepare the report for the relevant Independent Party.

(d) The Independent Directors (including the non-interested members of each Independent Party) will consider at least annually whether continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. *Record Keeping.* Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these Conditions were approved by the Required Majority under section 57(f).

12. *Director Independence.* No Independent Director (including the non-interested members of any Independent Party) of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an "affiliated person" (as defined in the Act) of any Affiliated Fund.

13. *Expenses.* The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the

distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. *Transaction Fees.*²⁹ Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by the Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Advisers, the Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i) in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B)(z), (ii) brokerage or underwriting compensation permitted by section 17(e) or 57(k) or (iii) in the case of the Advisers, investment advisory compensation paid in accordance with investment advisory agreements between the applicable Regulated Fund(s) or Affiliated Fund(s) and its Adviser.

15. *Independence.* If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders) when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the

Board's composition, size or manner of election.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-14787 Filed 7-12-21; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17027 and #17028; Indiana Disaster Number IN-00075]

Administrative Declaration of a Disaster for the State of Indiana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Indiana dated 07/06/2021.

Incident: Severe Storms and Flooding.
Incident Period: 06/18/2021 through 06/19/2021.

DATES: Issued on 07/06/2021.

Physical Loan Application Deadline Date: 09/07/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 04/07/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Jefferson, Monroe.

Contiguous Counties:

Indiana: Brown, Clark, Greene, Jackson, Jennings, Lawrence, Morgan, Owen, Ripley, Scott, Switzerland.

Kentucky: Carroll, Trimble.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	3.250

	Percent
Homeowners without Credit Available Elsewhere	1.625
Businesses with Credit Available Elsewhere	5.760
Businesses without Credit Available Elsewhere	2.880
Non-Profit Organizations with Credit Available Elsewhere	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.880
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17027 6 and for economic injury is 17028 0.

The States which received an EIDL Declaration # are Indiana, Kentucky.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2021-14771 Filed 7-12-21; 8:45 am]

BILLING CODE 8026-03-P

DEPARTMENT OF STATE

[Public Notice: 11464]

Notice of Public Meeting in Preparation for International Maritime Organization Meeting

The Department of State will conduct a public meeting at 10:00 a.m. on Friday, July 23, 2021, by way of teleconference. Members of the public may participate up to the capacity of the teleconference phone line, which will handle 500 participants. To access the teleconference line, participants should call (202) 475-4000 and use Participant Code: 138 541 34#.

The primary purpose of the meeting is to prepare for the 108th session of the International Maritime Organization's (IMO) Legal Committee (LEG 108) to be held remotely from July 26 to July 30, 2021. This is not a meeting of the Shipping Coordinating Committee.

The agenda items to be considered at the public meeting mirror those to be considered at LEG 108, and include:

- Adoption of the agenda
- Report of the Secretary-General on credentials
- Facilitation of the entry into force and harmonized interpretation of the 2010 HNS Protocol
- Fair treatment of seafarers
- Advice and guidance in connection with the implementation of IMO instruments

²⁹ Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

- Measures to prevent unlawful practices associated with the fraudulent registration and fraudulent registries of ships
- Regulatory scoping exercise and gap analysis of conventions emanating from the Legal Committee with respect to Maritime Autonomous Surface Ships (MASS)
- Unified Interpretation on the test for breaking the owner's right to limit liability under the IMO conventions
- Piracy
- Work of other IMO bodies
- Technical cooperation activities related to maritime legislation
- Review of the status of conventions and other treaty instruments emanating from the Legal Committee
- Any other business

Please note: IMO's Legal Committee may, on short notice, adjust the LEG 108 agenda to accommodate the constraints associated with the virtual meeting format. Any changes to the agenda will be reported to those who RSVP and those in attendance at the meeting.

Those who plan to participate may contact the meeting coordinator, Mr. Stephen Hubchen, by email at Stephen.K.Hubchen@uscg.mil, by phone at (202) 372-1198, or in writing at 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington DC 20593-7509. Members of the public needing reasonable accommodation should advise Mr. Hubchen not later than July 16, 2021. Requests made after that date will be considered, but might not be possible to fulfill.

Additional information regarding this and other IMO public meetings may be found at: <https://www.dco.uscg.mil/IMO>.

Emily A. Rose,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2021-14817 Filed 7-12-21; 8:45 am]

BILLING CODE 4710-09-P

DEPARTMENT OF STATE

[Public Notice 11463]

U.S. Stakeholder; Notice of Meeting

AGENCY: Department of State.

ACTION: Notice of meeting.

SUMMARY: The Department of State (Department) will host a virtual, open, U.S. stakeholder meeting, with remote participation only, to share information and obtain U.S. stakeholder input about the possible launch of negotiations to develop a global instrument to address ocean plastic pollution. There will be no in-person option for this meeting.

DATES: This U.S. stakeholder meeting will be held virtually on Tuesday, August 10, 2021, from 2 p.m. to 5 p.m. Eastern Daylight Time. Participants must register prior to the meeting at this link: <https://statedept.webex.com/statedept/j.php?RGID=r8f86337987086e15d01f9d0f0059bd91>.

The Department welcomes verbal comments from U.S. stakeholders during this meeting, with a time limit of two minutes per speaker. Written comments will not be accepted. There may be additional U.S. stakeholder meetings on this topic in the future: If you would like to be notified of future U.S. stakeholder meetings on this topic, please send your name, email address, and affiliation (if any) no later than 30 days after date of this notice to Geneva Craig at the address below.

FOR FURTHER INFORMATION CONTACT: Geneva Craig, Program Management Analyst, U.S. Department of State, 2201 C Street NW, Room 2726, Washington, DC 20520, (202) 531-3065, craigja@state.gov.

A participant requesting reasonable accommodation should notify Alea S. Ortiguerra, Conference Coordinator, U.S. Department of State, 2025 E Street NW, Washington, DC 20006, (202) 316-4874, OrtiguerraAS@state.gov.

SUPPLEMENTARY INFORMATION: The United Nations Environment Assembly (UNEA) has been considering how to combat ocean plastic pollution since its first meeting in 2014. UNEA is expected to discuss the possible launch of negotiations to develop a new global instrument to address this topic at the second meeting of the fifth session of UNEA (UNEA 5.2), tentatively scheduled for February 28 to March 2, 2022.

The U.S. Government is considering policy and legal issues related to this process, and the Department is seeking U.S. stakeholder input to inform our deliberations, particularly on the following questions:

- Should the United States support the development of a global instrument on ocean plastic pollution?
- If so, what should be the scope and objective(s) of such an instrument? What problem(s) or issue(s) should such an instrument address?
- What should be the form of such an instrument? For example, should it be a legal instrument with legally binding and non-legally binding provisions or a voluntary instrument?
- Should it take a top-down structure (i.e., common approach required for all countries) or a bottom-up structure (i.e., common objectives but allowance for flexible approaches to national implementation)?

- What could be an impactful role for stakeholders other than national governments, such as sub-national governments, industry, and civil society, in connection with this instrument?

- What other factors should be considered in negotiating such an instrument, such as the role of waste management, the role of any financial mechanism and/or technical assistance, flexibility for national circumstances, consideration of the full lifecycle of plastics, and economic and environmental impacts of alternatives to plastic?

- What sorts of provisions would be important or essential to include in a global instrument focused on ocean plastic pollution? What sorts of provisions would be problematic if they were included in such a global instrument?

Zachary A. Parker,

Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2021-14803 Filed 7-12-21; 8:45 am]

BILLING CODE 4710-09-P

DEPARTMENT OF STATE

[Public Notice 11455]

60-Day Notice of Proposed Information Collection: Petition To Classify Special Immigrant Under INA 203(b)(4) as Employee or Former Employee of the U.S. Government Abroad

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *September 13, 2021*.

You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to www.Regulations.gov. You can search for the document by entering "Docket Number: DOS-2021-0015" in the Search field. Then click the "Comment Now" button and complete the comment form.

- *Email:* PRA_BurdenComments@state.gov.
- *Phone:* Dylan Aikens at 202–485–7586.

You must include the DS form number (if applicable), information collection title, and OMB control number in any correspondence.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Petition to Classify Special Immigrant Under INA 203(b)(4) as Employee or Former Employee of the U.S. Government Abroad.
- *OMB Control Number:* 1405–0082.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* CA/VO.
- *Form Number:* DS–1884.
- *Respondents:* Aliens petitioning for immigrant visas under INA 203(b)(4) as a special immigrant described in INA section 101(a)(27)(D).
- *Estimated Number of Respondents:* 600.
- *Estimated Number of Responses:* 600.
- *Average Time per Response:* 10 minutes.
- *Total Estimated Burden Time:* 100 hours.
- *Frequency:* Once per petition.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

DS–1884 solicits information from petitioners claiming employment-based immigrant visa preference under section 203(b)(4) of the Immigration and Nationality Act on the basis of qualification as a special immigrant described in section 101(a)(27)(D) of the Immigration and Nationality Act. A

petitioner may file the DS–1884 petition within one year of notification by the Department of State that the Secretary has approved a recommendation for special immigrant status. DS–1884 solicits information that will assist the consular officer in ensuring that the petitioner is statutorily qualified to receive such status, including meeting the years of service and exceptional service requirements.

Methodology

The petitioner can obtain the form from consular posts abroad or through the Department's website, travel.state.gov. The application available on the Department's website allows an applicant to complete the application electronically and then print the application and submit it to post.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, Department of State.

[FR Doc. 2021–14825 Filed 7–12–21; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Libor Self-Assessment

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a new information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning renewal of a collection of information titled, “Libor Self-Assessment.” The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before August 12, 2021.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible.

You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0349, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include “OCC” as the agency name and “1557–0349” in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

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.

You may review comments and other related materials that pertain to this information collection¹ following the close of the 30-day comment period for this notice by the following method:

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Click on the “Information Collection Review” tab. Underneath the “Currently under Review” section heading, from the drop-down menu select “Department of Treasury” and then click “submit.” This information collection can be located by searching by OMB control number “1557–0349” or “Libor Self-Assessment.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

• For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer,

¹ On March 17, 2021, the OCC published a 60-day notice for this information collection, 86 FR 14681.

(202) 649-5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. OCC asks that OMB extend its approval of this collection.

Title: Libor Self-Assessment.

OMB Control No.: 1557-0349.

Type of Review: Regular.

Description: The expected cessation of the London InterBank Offered Rate (Libor) prompted the OCC to create a self-assessment tool for banks to use in preparing for the expected Libor cessation. The self-assessment tool may be used in assessing the appropriateness of a bank's Libor transition plan, in the execution of the plan by its management, and in related matters.

The Intercontinental Exchange Libor is a reference rate that is intended to reflect the cost of unsecured interbank borrowing. Libor is published daily in five currencies with seven maturities ranging from overnight to 12 months. It is used globally in the over-the-counter derivatives market, bonds, loan products, and securitizations. As of the end of 2016, \$199 trillion of financial instruments were exposed to U.S. dollar (USD) Libor as the primary reference rate.

While certain reference rates have ceased to be reported in the past, the significant exposure of the financial markets to Libor creates the need for banks to assess whether they are identifying applicable risks, preparing for the cessation, and successfully transitioning to replacement rates. Libor is referenced globally, and its cessation could affect banks of all sizes through direct or indirect exposure.

There is risk of market disruptions, litigation, and destabilized balance sheets if acceptable replacement rates do not attract sufficient market-wide acceptance or if contracts cannot seamlessly transition to new rates. A bank's risk exposure from expected Libor cessation depends on the bank's specific circumstances. Many community banks may not offer products or services that use Libor. However, community banks could have Libor exposure in positions such as Federal Home Loan Bank (FHLB)

borrowings, mortgage-backed securities, or bonds in the banks' investment portfolios.

Libor exposure can exist in all product categories and lines of business, both on or off the balance sheet, and in asset management activities. Risk can also emanate from third-party relationships because Libor is often used in pricing models, financial models, and in other parts of banks' infrastructure, such as core processing.

The ubiquity of Libor, present in over \$200T notional contracts, makes moving off the rate incredibly complicated. Many existing contracts do not include sufficient provisions in the event that Libor becomes unavailable (known as fallback provisions). Without adequate preparation, Libor cessation could cause market disruption and present risks to banks and their customers. In addition, fallback provision language does not sufficiently account for a permanent cessation of Libor. The Federal banking agencies published a statement communicating that banks should discontinue entering into contracts that use USD Libor as a reference rate as soon as practicable and in any event by the end of 2021 (with a few exceptions for orderly market support).²

Given that the OCC expects banks to discontinue making Libor loans by the end of 2021, the prevalence of Libor, and the remaining work to be done within the timeframe described above, the OCC is requesting renewal of the emergency clearance for this self-assessment tool to be made available to banks due to the immediate need and the brief duration of use, to help banks prepare for Libor-related risk.

Banks may use the self-assessment to determine whether they have risk management processes in place to identify and mitigate their Libor transition risks. Not all sections or questions will apply to all banks. Applicable risks (e.g., operational, compliance, strategic, and reputation) can be identified when scoping and completing Libor cessation preparedness assessments.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 1,096.

Estimated Annual Burden: 8,768 hours.

Frequency of Response: On occasion.

Comments: On March 17, 2021, the OCC published a 60-day notice for this information collection, 86 FR 14681. No

comments were received. Comments continue to be invited on:

(a) Whether the collections of information are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, 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 information collections on respondents, including through the use of automated collection techniques or other forms of information technology.

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2021-14772 Filed 7-12-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; International Regulation

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled "International Regulation—Part 28." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by August 12, 2021.

² <https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20201130a1.pdf>.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557-0102, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Fax:* (571) 465-4326.

Instructions: You must include "OCC" as the agency name and "1557-0102" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

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.

You may review comments and other related materials that pertain to this information collection¹ following the close of the 30-day comment period for this notice by the following method:

- **Viewing Comments Electronically:** Go to www.reginfo.gov. Click on the "Information Collection Review" tab. Underneath the "Currently under Review" section heading, from the drop-down menu select "Department of Treasury" and then click "submit." This information collection can be located by searching by OMB control number "1557-0102" or "International Regulation—Part 28." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the

Regulatory Information Service Center at (202) 482-7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649-5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, suite 3E-218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor.

"Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks OMB to extend its approval of this collection.

Title: International Regulation—Part 28.

OMB Control No.: 1557-0102.

Description: This submission covers an existing regulation and involves no change to the regulation or to the information collection requirements. The OCC requests only that OMB extend its approval of the information collection.

12 CFR 28.3 Filing Requirements for Foreign Operations of a National Bank—Notice Requirement

A national bank shall notify the OCC when it (1) files an application, notice, or report with the Board of Governors of the Federal Reserve System (FRB) to establish or open a foreign branch; or acquire or divest of an interest in, or close, an Edge corporation, Agreement corporation, foreign bank, or other foreign organization; or (2) opens a foreign branch, and no application or notice is required by the FRB for such transaction.

The OCC also has required an application pursuant to § 28.3(c) from a national bank seeking to join a foreign exchange, clearinghouse, or similar type of organization. In lieu of a notice, the OCC may accept a copy of an application, notice, or report submitted to another Federal agency that covers the proposed action and contains substantially the same information required by the OCC. A national bank shall furnish the OCC with any additional information the OCC may require in connection with the national bank's foreign operations.

12 CFR 28.14(c) Limitations Based Upon Capital of a Foreign Bank—Aggregation

A foreign bank shall aggregate business transacted by all Federal

branches and agencies with the business transacted by all state branches and agencies controlled by the foreign bank in determining its compliance with limitations based upon the capital of the foreign bank. A foreign bank shall designate one Federal branch or agency office in the United States to maintain consolidated information so that the OCC can monitor compliance.

12 CFR 28.15(d), (d)(1), (d)(2), and (f) Capital Equivalency Deposits

A foreign bank should require its depository bank to segregate its capital equivalency deposits (CED) on the depository bank's books and records. The instruments making up the CED that are placed in safekeeping at a depository bank to satisfy a foreign bank's CED requirement must be maintained pursuant to an agreement prescribed by the OCC that shall be a written agreement entered into with the OCC. Each Federal branch or agency shall maintain a capital equivalency account and keep records of the amount of liabilities requiring capital equivalency coverage in a manner and form prescribed by the OCC. A foreign bank's CED may not be reduced in value below the minimum required for that branch or agency without the prior approval of the OCC, but in no event may the value fall below the statutory minimum.

12 CFR 28.16(c) Deposit-Taking by an Uninsured Federal Branch—Application for an Exemption

A foreign bank may apply to the OCC for an exemption to permit an uninsured Federal branch to accept or maintain deposit accounts that are not listed in § 28.16(b). The request should describe the types, sources, and estimated amount of such deposits and explain why the OCC should grant an exemption, and how the exemption maintains and furthers the policies described in § 28.16(a).

12 CFR 28.16(d) Deposit-Taking by an Uninsured Federal Branch—Aggregation of Deposits

A foreign bank that has more than one Federal branch in the same state may aggregate deposits in all of its Federal branches in that state, but exclude deposits of other branches, agencies, or wholly owned subsidiaries of the bank. The Federal branch shall compute the average amount by using the sum of deposits as of the close of business of the last 30 calendar days ending with, and including, the last day of the calendar quarter, divided by 30. The Federal branch shall maintain records of

¹ On March 17, 2021, the OCC published a 60-day notice for this information collection, 86 FR 14679.

the calculation until its next examination by the OCC.

12 CFR 28.18(c)(1) Recordkeeping and Reporting—Maintenance of Accounts, Books, and Records

Each Federal branch or agency shall maintain a set of accounts and records reflecting its transactions that are separate from those of the foreign bank and any other branch or agency. The Federal branch or agency shall keep a set of accounts and records in English sufficient to permit the OCC to examine the condition of the Federal branch or agency and its compliance with applicable laws and regulations.

12 CFR 28.20(a)(1) Maintenance of Assets—General Rule

The OCC may require a foreign bank to hold certain assets in the state in which its Federal branch or agency is located.

12 CFR 28.22(e) Voluntary Liquidation—Reports of Examination

The Federal branch or agency shall send the OCC certification that all of its Reports of Examination have been destroyed or return its Reports of Examination to the OCC.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 52.

Estimated Total Annual Burden: 2,294.

Frequency of Response: On occasion.

On March 17, 2021, the OCC published a 60-day notice for this information collection, 86 FR 14679. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC'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 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2021-14776 Filed 7-12-21; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Supervisory Guidance on Stress Testing for Banking Organizations With Total Consolidated Assets of More Than \$10 Billion

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning renewal of its information collection titled, "Supervisory Guidance on Stress Testing for Banking Organizations with Total Consolidated Assets of More Than \$10 Billion."

DATES: Comments must be submitted on or before September 13, 2021.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0312, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Fax:* (571) 465-4326.

Instructions: You must include "OCC" as the agency name and "1557-0312" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change,

including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice (published following the close of this notice's comment period) for this collection by the following method:

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Click on the "Information Collection Review" tab. Underneath the "Currently under Review" section heading, from the drop-down menu select "Department of Treasury" and then click "submit." This information collection can be located by searching by OMB control number "1557-0312" or "Supervisory Guidance on Stress Testing for Banking Organizations with Total Consolidated Assets of More Than \$10 Billion." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, (202) 649-5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Title: Supervisory Guidance on Stress Testing for Banking Organizations with Total Consolidated Assets of More Than \$10 Billion.

OMB Control No.: 1557–0312.

Description: On May 17, 2012, the OCC, along with the Federal Deposit Insurance Corporation (FDIC) and the Board of Governors of the Federal Reserve (FRB), published guidance in the **Federal Register** on the use of stress testing as a means to better understand the range of a banking organization's ¹ potential risk exposures.² The OCC is now seeking to renew the information collection associated with that guidance.

The guidance provides an overview of how a banking organization should structure its stress testing activities to ensure that those activities fit into the banking organization's overall risk management. The purpose of the guidance is to outline broad principles for a satisfactory stress testing framework and describe how stress testing should be used. While the guidance is not intended to provide detailed instructions for conducting stress testing for any particular risk or business area, it does describe several types of stress testing activities and how they may be most appropriately used by banking organizations. The guidance also does not explicitly address the stress testing requirements imposed upon certain banking organizations by section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act.³

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 62.

Estimated annual burden: 16,120 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a

matter of public record. Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2021–14773 Filed 7–12–21; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8864

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 8864, Biodiesel and Renewable Diesel Fuels Credit.

DATES: Written comments should be received on or before September 13, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (737)800–

6149 or through the internet at Sara.L.Covington@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Biodiesel and Renewable Diesel Fuels Credit.

OMB Number: 1545–1924.

Form Number: 8864.

Abstract: Section 40A biodiesel and renewable diesel fuels credit is retroactively extended for fuel sold or used in calendar years 2018 through 2022. The credit consists of the Biodiesel credit, Renewable diesel credit, Biodiesel mixture credit, Renewable diesel mixture credit and Small Agri-biodiesel producer credit. Claim the credit for the tax year in which the sale or use occurs. Partnership, S Corporations, Cooperatives, estates, and trusts must file this form to claim the credit.

Current Actions: There are no changes being made to form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 934.

Estimated Time per Respondent: 4 hrs., 13 mins.

Estimated Total Annual Burden Hours: 3,941.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

¹ For purposes of this guidance, the term "banking organization" means national banks, federal savings associations, and federal branches and agencies supervised by the OCC; state member banks, bank holding companies, savings and loan holding companies, and all other institutions for which the Federal Reserve is the primary federal supervisor; and state nonmember banks, and all other institutions for which the FDIC is the primary federal supervisor.

² 77 FR 29458 (May 17, 2012).

³ Public Law 111–203, 124 Stat. 1376 (2010), as revised by the Economic Growth, Regulatory Relief, and Consumer Protection Act, Public Law 115–174, 132 Stat. 1296–1368 (2018), and codified at 12 U.S.C. 5365(i)(2).

other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 6, 2021.

Sara L. Covington,
IRS Tax Analyst.

[FR Doc. 2021-14821 Filed 7-12-21; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning preparer penalties-manual signature requirement.

DATES: Written comments should be received on or before September 13, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the regulation should be directed to Sara Covington, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (737) 800-6149 or through the internet, at Sara.L.Covington@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Preparer Penalties-Manual Signature Requirement.

OMB Number: 1545-1385.

Regulation Project Numbers: TD 8549.

Abstract: This regulation provides that persons who prepare U.S. Fiduciary income tax returns for compensation may, under certain conditions, satisfy the manual signature requirements by using a facsimile signature. However, they will be required to submit to the IRS a list of the names and identifying numbers of all fiduciary returns which are being filed with a facsimile signature.

Current Actions: There are no changes being made to this existing T.D. at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 20,000.

Estimated Time per Respondent: 1 hour, 12 min.

Estimated Total Annual Burden Hours: 24,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 07, 2021.

Sara L. Covington,
IRS Tax Analyst.

[FR Doc. 2021-14822 Filed 7-12-21; 8:45 am]

BILLING CODE 4830-01-P



FEDERAL REGISTER

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Part II

Office of Personnel Management

Department of the Treasury

Internal Revenue Service

Department of Labor

Employee Benefits Security Administration

Department of Health and Human Services

5 CFR Part 890

26 CFR Part 54

29 CFR Part 2590

45 CFR Parts 144, 147, 149, et al.

Requirements Related to Surprise Billing; Part I; Proposed Rule and Interim Final Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54****[REG-107706-21]****RIN 1545-BQ01****Requirements Related to Surprise Billing; Part I****AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Notice of proposed rulemaking.

SUMMARY: The IRS is proposing regulations that protect consumers from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances. Elsewhere in this issue of the **Federal Register**, the IRS is issuing the temporary regulations that correspond to this proposal at the same time that the Office of Personnel Management (OPM), the Employee Benefits Security Administration of the Department of Labor (DOL), and the Office of Consumer Information and Insurance Oversight of the Department of Health and Human Services (HHS) are issuing substantially similar interim final rules with request for comments. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES:

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 13, 2021.

Applicability date: It is proposed that these regulations apply on and after plan years beginning on or after January 1, 2022.

ADDRESSES: In commenting, please refer to file code REG-107706-21. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9909-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9909-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT: Kari DiCecco, (202) 317-5500, Internal Revenue Service, Department of the Treasury, for issues related to Surprise Billing.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

Background and Regulatory Impact Analysis

The Treasury Department and the IRS proposes to add §§ 54.9816-1, 54.9816-2, 54.9816-3, 54.9816-4, 54.9816-5, 54.9816-6, 54.9817-1, and 54.9822-1 to the Miscellaneous Excise Tax Regulations to protect consumers from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.

The temporary regulations published elsewhere in this issue of the **Federal Register** add §§ 54.9816-1T, 54.9816-2T, 54.9816-3T, 54.9816-4T, 54.9816-5T, 54.9816-6T, 54.9817-1T, and 54.9822-1T to the Miscellaneous Excise Tax Regulations. The proposed and temporary regulations are being published as part of a joint rulemaking with the OPM, DOL, and HHS. The text of temporary sections added elsewhere also serves as the text of the corresponding sections proposed in this document. The preamble to the temporary regulations contains the agency's rationale and provides a regulatory impact analysis.

Drafting Information

The principal author of this notice of proposed rulemaking is Kari DiCecco, Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations and Employment Taxes).

The proposed regulations, as well as the temporary regulations, have been developed in coordination with personnel from the OPM, DOL, and HHS.

List of Subjects in 26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph. 1.** The general authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ **Par. 2.** Section 54.9801-1 is revised to read as follows:

§ 54.9801-1 Basis and scope.

[The text of proposed § 54.9801-1 is the same as the text of § 54.9801-1T published elsewhere in this issue of the **Federal Register**.]

■ **Par. 3.** Section 54.9801-2 is amended by revising the introductory text to read as follows:

§ 54.9801-2 Definitions.

[The text of proposed § 54.9801-2 introductory text is the same as the text of § 54.9801-2T introductory text published elsewhere in this issue of the **Federal Register**.]

■ **Par. 4.** Section 54.9815-2719A is amended by revising paragraph (c) to read as follows:

§ 54.9815-2719A Patient protections.

[The text of proposed § 54.9815-2719A(c) is the same as the text of § 54.9815-2719AT(c) published elsewhere in this issue of the **Federal Register**.]

■ **Par. 5.** Sections 54.9816-1, 54.9816-2, 54.9816-3, 54.9816-4, 54.9816-5, 54.9816-6, 54.9816-7, 54.9817-1, and 54.9822-1 are added to read as follows:

Sec.

54.9816-1 Basis and scope.

54.9816-2 Applicability.

54.9816-3 Definitions.

54.9816-4 Preventing surprise medical bills for emergency services.

54.9816-5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

54.9816-6 Methodology for calculating qualifying payment amount.

54.9816-7 Complaints process for surprise medical bills regarding group health plans.

54.9817-1 Preventing surprise medical bills for air ambulance services.

54.9822–1 Choice of health care
professional.

* * * * *

§ 54.9816–1 Basis and scope.

[The text of proposed § 54.9816–1 is the same as the text of § 54.9816–1T published elsewhere in this issue of the **Federal Register**].

§ 54.9816–2 Applicability.

[The text of proposed § 54.9816–2 is the same as the text of § 54.9816–2T published elsewhere in this issue of the **Federal Register**].

§ 54.9816–3 Definitions.

[The text of proposed § 54.9816–3 is the same as the text of § 54.9816–3T published elsewhere in this issue of the **Federal Register**].

§ 54.9816–4 Preventing surprise medical bills for emergency services.

[The text of proposed § 54.9816–4 is the same as the text of § 54.9816–4T

published elsewhere in this issue of the **Federal Register**].

§ 54.9816–5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

[The text of proposed § 54.9816–5 is the same as the text of § 54.9816–5T published elsewhere in this issue of the **Federal Register**].

§ 54.9816–6 Methodology for calculating qualifying payment amount.

[The text of proposed § 54.9816–6 is the same as the text of § 54.9816–6T published elsewhere in this issue of the **Federal Register**].

§ 54.9816–7 Complaints process for surprise medical bills regarding group health plans.

[The text of proposed § 54.9816–7 is the same as the text of § 54.9816–7T published elsewhere in this issue of the **Federal Register**].

§ 54.9817–1 Preventing surprise medical bills for air ambulance services.

[The text of proposed § 54.9817–1 is the same as the text of § 54.9817–1T published elsewhere in this issue of the **Federal Register**].

§ 54.9822–1 Choice of health care professional.

[The text of proposed § 54.9822–1 is the same as the text of § 54.9822–1T published elsewhere in this issue of the **Federal Register**].

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2021–14382 Filed 7–6–21; 4:15 pm]

BILLING CODE 4830–01–P

**OFFICE OF PERSONNEL
MANAGEMENT****5 CFR Part 890**

RIN 3206-AO30

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD9951]

RIN 1545-BQ04

DEPARTMENT OF LABOR**Employee Benefits Security
Administration****29 CFR Part 2590**

RIN 1210-AB99

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****45 CFR Parts 144, 147, 149, and 156**

[CMS-9909-IFC]

RIN 0938-AU63

**Requirements Related to Surprise
Billing; Part I**

AGENCY: Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document sets forth interim final rules implementing certain provisions of the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021. These interim final rules amend and add provisions to existing rules under the Internal Revenue Code, the Employee Retirement Income Security Act, the Public Health Service Act, and the Federal Employees Health Benefits Act. These interim final rules implement provisions of the No Surprises Act that protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers of air

ambulance services, under certain circumstances. In this rulemaking, the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments) are issuing interim final rules with largely parallel provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage. HHS is also issuing in this rulemaking additional interim final rules that apply to emergency departments of hospitals and independent freestanding emergency departments, health care providers and facilities, and providers of air ambulance services related to the protections against surprise billing. The Office of Personnel Management (OPM) is issuing in this rulemaking interim final rules that specify how certain provisions of the No Surprises Act apply to health benefits plans offered by carriers under the Federal Employees Health Benefits Act (FEHBA).

DATES: *Effective date:* These regulations are effective on September 13, 2021.

Applicability date: The regulations are generally applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The HHS-only regulations that apply to health care providers, facilities, and providers of air ambulance services are applicable beginning on January 1, 2022. The OPM-only regulations that apply to health benefits plans are applicable to contract years beginning on or after January 1, 2022.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 7, 2021.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments and OPM. Please do not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, refer to file code CMS-9909-IFC. Because of staff and resource limitations, we cannot accept

comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at <https://www.regulations.gov> by entering the file code in the search window and then clicking on "Comment".

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9909-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9909-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Padma Babubhai Shah, Office of Personnel Management, at 202-606-4056; Kari DiCecco, Internal Revenue Service, Department of the Treasury, at 202-317-5500; Matt Litton or David Sydlík, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; Lindsey Murtagh, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301-492-4106.

Customer Service Information:

Information from OPM on health benefits plans offered under the Federal Employees Health Benefits (FEHB) Program can be found on the OPM website (www.opm.gov/healthcare-insurance/healthcare/). Individuals interested in obtaining information from the DOL concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website (www.dol.gov/ebsa). In addition, information from HHS on private health insurance coverage and coverage provided by non-federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: Comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

A. Patient Protections and Requirements Related to Emergency Services Under Section 2719A of the Public Health Service Act

The Patient Protection and Affordable Care Act (Pub. L. 111–148), was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010 (these statutes are collectively known as the “Affordable Care Act” or “ACA”). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. Sections 2701 through 2728 of the PHS Act are incorporated into ERISA and the Code.

Under section 2719A of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, if a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group or individual health insurance coverage provides any benefits with respect to emergency services in an emergency department of a hospital, the plan or issuer must cover emergency services without the individual or the health care provider having to obtain prior authorization (including when the emergency services are provided out-of-network) and without regard to whether the health care provider furnishing the emergency services is an in-network provider with

respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or coordination of benefits, an affiliation or waiting period permitted under the Code, ERISA, and the PHS Act, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services. In addition, carriers offering FEHB plans must comply with requirements described in section 2719A of the PHS Act in the same manner as they apply to a plan or issuer.

For purposes of the requirements under section 2719A of the PHS Act, emergency services mean, with respect to an emergency medical condition, (1) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and (2) that is within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of the Social Security Act to stabilize the patient.

Regulations implementing section 2719A of the PHS Act include these consumer protections.² Section 2719A of the PHS Act did not prohibit balance billing. Balance billing refers to the practice of out-of-network providers billing patients for the difference between (1) the provider's billed charges, and (2) the amount collected from the plan or issuer plus the amount collected from the patient in the form of cost sharing (such as a copayment, coinsurance, or amounts paid toward a deductible). To avoid the circumvention of the protections of section 2719A of the PHS Act, in the implementing regulations, the Departments determined it was necessary that a reasonable amount be paid by a plan or issuer before a patient becomes responsible for a balance billing amount.³ Therefore, under the

Departments' final regulations published in the **Federal Register** on November 18, 2015 (Patient Protections Final Rule), a plan or issuer satisfies the out-of-network emergency care cost-sharing limitations in the statute if it provides benefits for out-of-network emergency services in an amount at least equal to the greatest of the following three amounts (adjusted for in-network cost sharing): (1) The median amount negotiated with in-network providers for the emergency service; (2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable (UCR) amount); or (3) the amount that would be paid under Medicare Part A or Part B for the emergency service (collectively, minimum payment standards).⁴ The Departments' regulations clarify that the cost-sharing requirements create a minimum payment requirement for the plan or issuer.⁵ The Departments also clarified that the cost-sharing requirements do not prohibit a group health plan or health insurance issuer from providing benefits with respect to an emergency service that are greater than the amounts specified in the regulations. However, those regulations address balance billing with respect to only emergency services and, even in that context, they serve only to minimize the amount of a balance bill by requiring that plans and issuers must pay a reasonable amount for emergency services before a patient becomes responsible for a balance billing amount. Prior to the enactment of the No Surprises Act, these minimum payment standards were the only federal consumer protections to reduce potential amounts of balance billing for individuals enrolled in group health plans and group and individual health insurance coverage.

⁴ 26 CFR 54.9815–2719A(b)(3); 29 CFR 2590.715–2719A(b)(3); 45 CFR 147.138(b)(3).

⁵ If state law prohibits balance billing, or in cases in which a group health plan or health insurance issuer is contractually responsible for balance billing amounts, plans and issuers are not required to satisfy the minimum payment standards set forth in the regulations, but may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in-network. See 26 CFR 54.9815–2719A(b)(3)(iii); 29 CFR 2590.715–2719A(b)(3)(iii); 45 CFR 147.138(b)(3)(iii); FAQs about Affordable Care Act Implementation (Part I), Q15 (Sept. 20, 2010), available at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs>; www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca-implementation-faqs.html.

² 26 CFR 54.9815–2719A(b); 29 CFR 2590.715–2719A(b); 45 CFR 147.138(b).

³ 75 FR 37188, 37194 (June 28, 2010); see also 80 FR 72192 (Nov. 18, 2015). Additional clarification of these rules was also provided in 2018. See 83 FR 19431 (May 3, 2018).

¹ The term “group health plan” includes both insured and self-insured group health plans.

The No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act, which expand the patient protections related to emergency services under section 2719A of the PHS Act, in part, by providing additional consumer protections related to balance billing.⁶ The No Surprises Act amended section 2719A of the PHS Act to include a sunset provision effective for plan years beginning on or after January 1, 2022, when the new protections under the No Surprises Act take effect.

Additionally, the No Surprises Act redefined the patient protections regarding choice of health care professional from section 2719A(a), (c), and (d) of the PHS Act at new section 9822 of the Code, section 722 of ERISA, and section 2799A–7 of the PHS Act. If a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, these provisions permit individuals to designate any participating primary care providers available to accept them, including pediatricians, and prohibit the plan or issuer from requiring authorization or referral for obstetrical or gynecological care.

B. Surprise Billing and the Need for Greater Consumer Protections

Most group health plans, and health insurance issuers offering group or individual health insurance coverage, have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services.⁷ By contrast, providers and facilities that are not part of a plan or issuer's network (nonparticipating providers) usually charge higher amounts than the contracted rates that plans and issuers have negotiated with participating providers and facilities. When a participant, beneficiary, or enrollee receives care from a nonparticipating provider, the individual's plan or issuer may decline to pay for the service or may pay an amount that is lower than the provider's billed charges, and may subject the

individual to greater cost-sharing requirements than would have been charged had the services been furnished by a participating provider. Prior to the No Surprises Act, the nonparticipating provider could generally balance bill the individual for the difference between the provider's billed charges and the sum of the amount paid by the plan or issuer and the cost sharing paid by the individual, unless otherwise prohibited by state law.

A balance bill may come as a surprise for the individual. A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a covered person receives medical services from a provider or facility that, usually unknown to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. Surprise billing occurs both for emergency and non-emergency care. In an emergency, a person usually goes (or is taken by emergency transport) to a nearby emergency department. Even if they go to a participating hospital or facility for emergency care, they may receive care from nonparticipating providers working at that facility. For non-emergency care, a person may choose a participating facility (and possibly even a participating provider), but not know that at least one provider involved in their care (for example, an anesthesiologist or radiologist) is a nonparticipating provider. In either circumstance, the person might not be in a position to choose the provider, or to ensure that the provider is a participating provider. Therefore, in addition to a bill for their cost-sharing amount, which tends to be higher for out-of-network services, the person might receive a balance bill from the nonparticipating provider or facility. This scenario also plays out frequently for air ambulance services, where individuals generally do not have the ability to select a provider of air ambulance services, and, therefore, have little or no control over whether the provider is in-network with their plan or coverage.

When individuals are unable to avoid nonparticipating providers, it raises health care costs and exposes patients to financial risk.⁸ The evidence suggests that the ability to balance bill is used as leverage by some providers to obtain higher in-network payments, which results in higher premiums, higher cost sharing for individuals, and increased

health care expenditures overall.⁹ Studies have shown that surprise bills can be large. For example, a recent study found that physicians collected, on average, 65 percent of the total charged amount for emergency department visits that likely included surprise bills, compared to 52 percent of the total charged amount for emergency department visits that likely did not include surprise bills. The study also found that nine percent of the individuals who likely received surprise bills paid physicians an amount more than \$400, which may cause financial hardship to many individuals.¹⁰ In addition, out-of-network cost sharing and payments for surprise bills usually do not count towards an individual's deductible and maximum out-of-pocket expenditure limits. Therefore, individuals with surprise bills may have difficulty reaching those limits, even after a significant health care event.

Another study using claims data from a large commercial issuer for the period 2010–2016 found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and the incidence increased from 32.3 percent in 2010 to 42.8 percent in 2016. The average potential amount of surprise medical bills also increased from \$220 in 2010 to \$628 in 2016. During the same period, 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill, increasing from 26.3 percent in 2010 to 42 percent in 2016, and the average potential surprise medical bill increased from \$804 to \$2,040.¹¹

Although some states have enacted laws to reduce or eliminate balance billing, these efforts have created a patchwork of consumer protections. Even within a state that has enacted such protections, those protections typically apply only to individuals enrolled in individual and group health insurance coverage, as ERISA generally

⁶ These new protections apply regardless of whether the plan or coverage is a grandfathered health plan under section 1251 of the Affordable Care Act. The No Surprises Act also amended 5 U.S.C. 8902(p) to ensure that covered individuals enrolled in FEHB plans receive these protections.

⁷ These interim final rules refer to providers both in terms of their participation (participating provider) and in terms of a network (in-network provider). In both situations, the intent is to refer to a provider that has a contractual relationship or other arrangement with a plan or issuer to provide health care items and services for participants, beneficiaries, and enrollees of the plan or issuer.

⁸ Cooper Z et al., Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians, *Health Affairs* 39, No. 1, 2020. doi: 10.1377/hlthaff.2019.00507.

⁹ See Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 20173623; Duffy, E. et al., Policies to Address Surprise Billing Can Affect Health Insurance Premiums. *The American Journal of Managed Care* 26.9 (2020): 401–404.; and Brown E.C.F., et al., The Unfinished Business of Air Ambulance Bills, *Health Affairs Blog* (March 26, 2021), DOI: 10.1377/hblog20210323.911379, available at <https://www.healthaffairs.org/doi/10.1377/hblog20210323.911379/full/>.

¹⁰ Biener, A. et al., Emergency Physicians Recover a Higher Share of Charges From Out-Of-Network Care Than From In-Network Care, *Health Affairs* 40, No. 4 (2021): 622–628.

¹¹ Sun EC, Mello MM, Moshfegh J, Baker LC, Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. *JAMA Intern Med.* 2019; 179(11):1543–1550 (2019). doi:10.1001/jamainternmed.2019.3451.

preempts state laws that regulate self-insured group health plans sponsored by private employers. In addition, states are limited in their ability to address surprise bills that involve an out-of-state provider.

Surprise medical bills can lead to medical debt for individuals who have difficulty paying their bills. The impact is most keenly felt by those communities experiencing poverty and other social risk factors, as surprise medical bills and medical debt can negatively affect individuals' abilities to eliminate debt and create wealth, and ultimately can affect a family for generations.¹² A recent survey reported that while 68 percent of respondents said that it was difficult to pay a surprise bill, the likelihood of such difficulty was higher for middle income respondents (77 percent) and African Americans (74 percent). In addition, while 11 percent of survey respondents were unable to pay the surprise bill, 21 percent of low income respondents, 19 percent of African Americans, and 17 percent of respondents in rural areas were unable to do so.¹³ In addition, individuals are often confused by medical bills. A 2016 survey found that 61 percent of individuals are confused by medical bills, and for 49 percent of individuals surveyed, the amount owed was a surprise.¹⁴ These challenges are exacerbated for underserved communities, which are more likely to experience poor communication, underlying mistrust of the medical system, and lower levels of patient engagement than other populations.¹⁵

¹² Taylor, J. Racism, inequality, and health care for African Americans. The Century Foundation: Report (December 19, 2019). <https://tcf.org/content/report/racism-inequality-health-care-african-americans/>; Chavis, B. Op-Ed: Big insurance must help end surprise medical billing. *blackpressUSA* (February 24, 2020).

¹³ Families USA, Surprise Medical Bills, Results from a National Survey, November 2019. <https://familiesusa.org/wp-content/uploads/2019/11/Surprise-Billing-National-Poll-Report-FINAL.pdf>.

¹⁴ Gooch, Kelly. 61% of patients confused by medical bills, survey finds. *Becker's Hospital Review* (July 14, 2016). <https://www.beckershospitalreview.com/finance/61-of-patients-confused-by-medical-bills-survey-finds.html>.

¹⁵ See Butler S, Sherriff N. How poor communication exacerbates health inequities and what to do about it. Brookings Institution: Report (February 22, 2021). <https://www.brookings.edu/research/how-poor-communication-exacerbates-health-inequities-and-what-to-do-about-it/>; Hamel, L., Lopes, L., Muñana, C., Artiga, S., Brodie, M. Race, Health, and COVID-19: The Views and Experiences of Black Americans. Kaiser Family Foundation (October 2020). <https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>; Shen M.J., Peterson E.B., Costas-Muñiz R. et al. The Effects of Race and Racial Concordance on Patient-Physician Communication: A Systematic Review of the Literature. *J. Racial and*

Effective, culturally, and linguistically tailored communication at appropriate literacy levels, coupled with policies that address the social risk factors and other barriers underserved communities face to accessing, trusting, and understanding health care costs and coverage, can reduce disparities and promote health equity.¹⁶

Communication among providers, plans, consumers, communities, and consumer advocates must be consistent with and reinforce all relevant consumer protections related to surprise bills. Such communication must be accessible, linguistically tailored, and at an appropriate literacy level. This includes compliance with requirements to provide effective communication for individuals with disabilities under the Americans with Disabilities Act of 1990,¹⁷ section 504 of the Rehabilitation Act of 1973¹⁸ and, where applicable, section 1557 of the Affordable Care Act,¹⁹ as well as compliance with race, color, and national origin protections under title VI of the Civil Rights Act of 1964²⁰ and section 1557 of the Affordable Care Act. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, or disability in covered health programs or activities, including requiring covered entities to take reasonable steps to ensure meaningful access for individuals with limited English proficiency.

On January 20, 2021, President Biden issued Executive Order 13985, "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,"²¹ 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. Executive Order 13985 also directs HHS to assess whether, and to what extent, its programs and policies

Ethnic Health Disparities 5, 117–140 (2018). <https://doi.org/10.1007/s40615-017-0350-4>.

¹⁶ Pérez-Stable EJ, El-Toukhy S. Communicating with diverse patients: How patient and clinician factors affect disparities. *Patient Educ Couns*. 2018;101(12):2186–2194. doi:10.1016/j.pec.2018.08.021; McNally, M. Confronting disparities in access to healthcare for underserved populations. *MedCity News* (February 22, 2021). <https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/>.

¹⁷ 42 U.S.C. 12101 et seq.

¹⁸ 29 U.S.C. 794 and 794d.

¹⁹ 42 U.S.C. 18116(a).

²⁰ 42 U.S.C. 2000d.

²¹ 86 FR 7009 (Jan. 25, 2021).

perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups. Consistent with Executive Order 13985, regulations issued pursuant to the No Surprises Act must ensure that communication from plans, issuers, providers, facilities, and providers of air ambulance services recognizes these inequities and upholds all relevant consumer protections. Regulations issued pursuant to the No Surprises Act should ensure that all individuals, particularly those from underserved and minority communities, trust and believe information they receive related to costs and network coverage. Regulations and policies should enable and encourage regulated entities to address barriers to accessing care, including mistrust of the health care system. They should also encourage entities to communicate with individuals in a language they can understand, in a respectful way that addresses cultural differences, and at an appropriate literacy level. To ensure all consumers, particularly those in minority and underserved communities, are able to understand and benefit from these consumer protections, deliberate attention must be paid to the unique barriers and challenges underserved communities face in understanding and accessing health care. The Departments seek comment from those who are members of, advocate for, and work with underserved communities regarding the impact of these interim final rules.

C. Preventing Surprise Medical Bills Under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which included the No Surprises Act, was signed into law. The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.²²

The CAA added provisions that apply to group health plans and health insurance issuers in the group and individual market in a new Part D of title XXVII of the PHS Act, and also added new provisions to part 7 of ERISA, and subchapter B of chapter 100 of the Code. Section 102 of the No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act, which contain limitations on cost sharing, and requirements for initial payments for emergency services and for non-emergency services provided by

²² Public Law 116–260.

nonparticipating providers at certain participating health care facilities. Section 103 of the No Surprises Act amended section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act to establish an independent dispute resolution (IDR) process that allows plans and issuers and nonparticipating providers and nonparticipating emergency facilities to resolve disputes over out-of-network rates. Section 105 of the No Surprises Act added section 9817 of the Code, section 717 of ERISA, and section 2799A–2 of the PHS Act, which contain limitations on cost sharing and requirements for initial payments to nonparticipating providers of air ambulance services, and allow plans and issuers and such providers of air ambulance services to access the IDR process. The CAA also amended the FEHBA, as discussed in more detail in section I.D. of this preamble.

The CAA provisions that apply to health care providers and facilities and providers of air ambulance services, such as cost-sharing requirements, prohibitions on balance billing for certain items and services, and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in a new part E.

The Departments are issuing regulations in several phases implementing provisions of title I (No Surprises Act) and title II (Transparency) of Division BB of the CAA. Later this year, the Departments intend to issue regulations regarding the federal IDR process (sections 103 and 105 of Division BB), patient protections through transparency and the patient-provider dispute resolution process (section 112), and price comparison tools (section 114). The Departments also intend to undertake rulemaking this year to propose the form and manner in which plans, issuers, and providers of air ambulance services would report information regarding air ambulance services (section 106). In addition, HHS intends to undertake rulemaking to implement requirements on health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to disclose and report information regarding direct or indirect compensation provided to agents and brokers (section 202(c)), as well as provisions related to HHS enforcement of requirements on issuers, non-federal governmental group health plans, providers, facilities, and providers of air ambulance services.

The CAA also includes provisions regarding transparency in plan and insurance identification cards (section

107), continuity of care (section 113), accuracy of provider network directories (section 116), and prohibition on gag clauses (section 201) that are applicable for plan years beginning on or after January 1, 2022; and pharmacy benefit and drug cost reporting (section 204) that is required by December 27, 2021. The Departments intend to undertake rulemaking to fully implement these provisions, but rulemaking regarding some of these provisions might not occur until after January 1, 2022. The Departments note that any such rulemaking to fully implement these provisions will include a prospective applicability date that provides plans, issuers, providers, and facilities, as applicable, a reasonable amount of time to comply with new or clarified requirements. Until rulemaking to fully implement these provisions is finalized and effective, plans and issuers are expected to implement the requirements using a good faith, reasonable interpretation of the statute. The Departments intend to issue guidance in the near future regarding their expectations related to good faith compliance with these provisions.

D. Preventing Surprise Medical Bills for Federal Employees Health Benefits Plans

The No Surprises Act also amended the FEHBA, 5 U.S.C. 8901 *et seq.*, by adding a new subsection (p) to 5 U.S.C. 8902. Under this new provision, each FEHB Program contract must require a carrier to comply with provisions of sections 9816, 9817, and 9822 of the Code; sections 716, 717, and 722 of ERISA; and sections 2799A–1, 2799A–2, and 2799A–7 of the PHS Act (as applicable) in the same manner as they apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage. Likewise, the provisions of sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act apply to health care providers, facilities, and providers of air ambulance services with respect to covered individuals in FEHB plans in the same manner as they apply to participants, beneficiaries, or enrollees in group health plans or coverage offered by health insurance issuers.

OPM is charged with administering the FEHB Program and maintains oversight and enforcement authority with respect to FEHB health benefits plans, which are federal governmental plans. Generally, under 5 U.S.C. 8902(p), each FEHB contract must require a carrier to comply with certain PHS Act, ERISA, and Code requirements in the same manner as they apply to a

group health plan or health insurance issuer.

II. Executive Summary

These interim final rules implement provisions of the No Surprises Act that: (1) Apply to group health plans, health insurance issuers offering group or individual health insurance coverage, and carriers in the FEHB Program to provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers at certain participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services; (2) prohibit nonparticipating providers, health care facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations, and permit these providers and facilities to balance bill individuals if certain notice and consent requirements in the No Surprises Act are satisfied; (3) require certain health care facilities and providers to provide disclosures of federal and state patient protections against balance billing; (4) recodify certain patient protections that initially appeared in the ACA and that the No Surprises Act applies to grandfathered plans; and (5) set forth complaints processes with respect to violations of the protections against balance billing and out-of-network cost sharing under the No Surprises Act.

These interim final rules protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances. Among other requirements, these interim final rules require emergency services to be covered without any prior authorization, without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services, and without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits or a permitted affiliation or waiting period. Additionally, emergency services include certain services in an emergency department of a hospital or an independent freestanding emergency department, as well as post-stabilization services in certain instances.

With respect to emergency services, air ambulance services furnished by nonparticipating providers, and non-

emergency services furnished by nonparticipating providers at participating facilities, these interim final rules limit cost sharing for out-of-network services to in-network levels, require such cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing, as required by the No Surprises Act.

These interim final rules specify that cost-sharing amounts for such services furnished by nonparticipating emergency facilities and nonparticipating providers at participating facilities must be calculated based on one of the following amounts: (1) An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the plan's or issuer's median contracted rate, referred to as the qualifying payment amount (QPA). Cost-sharing amounts for air ambulance services provided by nonparticipating providers must be calculated using the lesser of the billed charge or the QPA, and the cost-sharing requirement that would apply if such services were provided by a participating provider.

Under these interim final rules, balance billing for services covered by the rules generally is prohibited, and the total amount to be paid to the provider or facility, including any cost sharing, is based on: (1) An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; (3) if there is no such applicable All-Payer Model Agreement or specified state law, an amount agreed upon by the plan or issuer and the provider or facility; or (4) if none of those three conditions apply, an amount determined by an IDR entity.

In general, under the No Surprises Act and these interim final rules, the protections that limit cost sharing and prohibit balance billing do not apply to certain post-stabilization services, or to certain non-emergency services performed by nonparticipating providers at participating health care facilities, if the provider or facility provides notice to the participant, beneficiary, or enrollee, and obtains the individual's consent to waive the balance billing protections. However, providers and facilities may not provide

such notice or seek consent from individuals in certain circumstances where surprise bills are likely to occur, such as for ancillary services provided by nonparticipating providers in connection with non-emergency care in a participating facility. In such circumstances, balance billing is prohibited, and the other protections of the No Surprises Act, such as in-network cost-sharing requirements, continue to apply.

Neither the No Surprises Act, nor these interim final rules, universally protect individuals from every high or unexpected medical bill. For example, an individual may be enrolled in a group health plan or health insurance coverage that provides little or no coverage for their particular health care condition or the items and services necessary to treat that condition. In addition, balance billing continues to be permitted, unless prohibited by state law or contract, in circumstances where these interim final rules do not apply, such as for non-emergency items or services provided at facilities that are not included within the definition of health care facility in these interim final rules. Nonetheless, the No Surprises Act and these interim final rules provide relief from some of the more common scenarios where a participant, beneficiary, or enrollee might otherwise be faced with high and unexpected medical costs.

These interim final rules establish a complaints process for receiving and resolving complaints related to these new balance billing protections.

These interim final rules also implement the requirement of the No Surprises Act that certain health care providers and facilities make publicly available, post on a public website, and provide a one-page notice to individuals regarding: (1) The requirements and prohibitions applicable to the provider or facility under sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations; (2) any applicable state balance billing requirements; and (3) how to contact appropriate state and federal agencies if the individual believes the provider or facility has violated the requirements described in the notice.

Section 116 of the No Surprises Act also added section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act, which include similar disclosure requirements applicable to plans and issuers. In general, under these provisions, plans and issuers must make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or

service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act apply, information on the requirements applied under these aforementioned sections, as applicable; on the requirements and prohibitions applied under sections 2799B–1 and 2799B–2 of the PHS Act; on other applicable state laws on out-of-network balance billing; and on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing. These disclosure requirements are applicable for plan years beginning on or after January 1, 2022. To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a model disclosure notice that health care providers, facilities, group health plans, and health insurance issuers may, but are not required to, use to satisfy the disclosure requirements regarding the balance billing protections. The Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act, if all other applicable requirements are met. In addition, HHS will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 2799B–3 of the PHS Act and 45 CFR 149.430, if all other applicable PHS Act requirements are met. The Departments may address the requirements under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act, as added by the No Surprises Act, in more detail in future guidance or rulemaking. Until further guidance is issued, plans and issuers are expected to implement the requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act using a good faith, reasonable interpretation of the law. The Departments will take into account the statutory applicability date and the timeframe for implementation when determining good faith compliance with the law.

These interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022, as

well as to health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022.

In the OPM interim final rules included in this rulemaking, OPM adopts all provisions of the Departments' interim final rules that address the sections of the Code, ERISA, and the PHS Act that are referenced in 5 U.S.C. 8902(p). In the OPM interim final rules, OPM defines terms unique to the FEHB Program, adapts some of the Departments' rules as necessary to properly integrate with the existing FEHB Program regulatory and contractual structure, sets forth the circumstances in which OPM will enforce these rules against FEHB carriers, and sets forth the types of court actions involving the FEHB Program that may be brought against OPM with respect to the No Surprises Act.

In effectuating compliance with 5 U.S.C. 8902(p), FEHB contract terms that relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) supersede and preempt state law or local law, or any regulation issued thereunder, which relates to health insurance or plans.²³ OPM contracts with FEHB carriers may include terms that adopt state law as governing for a particular purpose.

III. Overview of the Interim Final Rules—Departments of HHS, Labor, and the Treasury

A. Definitions

The provisions of the Code, ERISA, and the PHS Act added by the No Surprises Act, as well as these interim final rules, include defined terms that are specific to the requirements and implementation of the law. Definitions of these key terms are described throughout this preamble. These terms help define the scope of the balance billing protections and how cost-sharing amounts and payment levels are determined.

The Departments note that these interim final rules define the term “physician or health care provider” to mean a physician or other health care provider who is acting within the scope of practice of that provider’s license or certification under applicable state law, but the definition specifically excludes providers of air ambulance services. The Departments recognize that, although the No Surprises Act does not define “provider,” it uses the term in a manner that includes providers of air ambulance services in some provisions. For

example, the No Surprises Act added section 2799B–4 of the PHS Act, which specifically includes providers of air ambulance services when referencing providers. However, certain other provisions in the No Surprises Act apply only to providers of air ambulance services, or apply to health care providers generally, but by their terms are inapplicable to providers of air ambulance services. As an example of the latter, the No Surprises Act added section 2799B–2 of the PHS Act, which generally prohibits balance billing by nonparticipating health care providers furnishing non-emergency services at participating health care facilities. Although this provision does not explicitly exclude providers of air ambulance services, providers of air ambulance services would not furnish non-emergency services at participating health care facilities. Therefore, the provision does not apply to providers of air ambulance services (such providers are, however, prohibited from balance billing under section 2799B–5 of the PHS Act). Similarly, section 2799B–3 of the PHS Act, which requires a health care provider to inform individuals of the requirements and prohibitions on such health care provider in sections 2799B–1 and 2799B–2 of the PHS Act (neither of which apply to providers of air ambulance services), does not by its terms apply to providers of air ambulance services. Therefore, these interim final rules define “physician or health care provider” to exclude providers of air ambulance services, in order to help clarify which provisions of the No Surprises Act and interim final rules apply to providers of air ambulance services. In instances where provisions under the No Surprises Act, as implemented in these interim final rules, apply to providers of air ambulance services, the provisions explicitly reference air ambulance providers. Conversely, where providers of air ambulance services are not explicitly mentioned, the provisions do not apply.

The Departments seek comment on the terms defined in these interim final rules, including the appropriateness and usability of the definitions, and whether additional terms should be defined in future rulemaking.

B. Preventing Surprise Medical Bills

1. Scope of the New Surprise Billing Protections

i. Emergency Services

Under section 9816(a) of the Code, section 716(a) of ERISA, and section 2799A–1(a) of the PHS Act, and these interim final rules, if a group health

plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services as defined in these interim final rules and such coverage must be provided in accordance with these interim final rules.

A plan or issuer providing coverage of emergency services must do so without the individual or the health care provider having to obtain prior authorization (including when the emergency services are provided out-of-network) and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition as defined in these interim final rules), an affiliation or waiting period as permitted under the Code, ERISA, or the PHS Act, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on coverage for emergency services received from nonparticipating providers or nonparticipating emergency facilities that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers or participating emergency facilities. In addition, such plan or health insurance coverage must comply with the requirements regarding cost sharing, payment amounts, and processes for resolving billing disputes described elsewhere in this preamble.

The terms “emergency medical condition,” “emergency services,” and “to stabilize” generally have the meaning given to them under the Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act.²⁴ Emergency services include: (1) An appropriate medical screening examination that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, including ancillary services

²³ 5 U.S.C. 8902(m)(1); see *Coventry Health Care of Missouri, Inc. v. Nevils*, 137 S. Ct. 1190 (2017).

²⁴ 42 U.S.C. 1395dd.

routinely available to the emergency department, to evaluate whether an emergency medical condition exists; and (2) such further medical examination and treatment as may be required to stabilize the individual (regardless of the department of the hospital in which the further medical examination and treatment is furnished) within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department.

Under section 2719A of the PHS Act, emergency services were defined to include: (1) A medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and (2) such further medical examination and treatment as are required under section 1867 of the Social Security Act to stabilize the patient within the capabilities of the staff and facilities available at the hospital. HHS has previously interpreted the obligations on hospitals under EMTALA to provide medical examination and stabilization services to end when a patient is formally admitted in good faith.²⁵ Section 9816(a) of the Code, section 716(a) of ERISA, and section 2799A–1(a) of the PHS Act expand the definition of emergency services (as compared to section 2719A of the PHS Act) to include stabilization services “regardless of the department of the hospital in which the further medical examination and treatment is furnished.” Therefore, the definition of emergency services in these interim final rules includes pre-stabilization services that are provided after the patient is moved out of the emergency department and admitted to a hospital, and these services will be subject to the protections of the No Surprises Act.

Section 102 of the No Surprises Act further broadens the definition of emergency services to include emergency services provided at an independent freestanding emergency department. An independent freestanding emergency department is a health care facility (not limited to those described in the definition of health care facility at section 9816(b)(2)(A)(ii) of the Code, section 716(b)(2)(A)(ii) of ERISA, and section 2799A–1(b)(2)(A)(ii) of the PHS Act, as applicable) that provides emergency services, and is geographically separate and distinct

from a hospital, and separately licensed as such by a state. The definition of “independent freestanding emergency department” is intended to include any health care facility that is geographically separate and distinct from a hospital, and that is licensed by a state to provide emergency services, even if the facility is not licensed under the term “independent freestanding emergency department.”

Regulation of health care facilities varies by state. In particular, state regulation of urgent care centers varies significantly, and is evolving as these types of centers become more common.²⁶ If under state licensure laws, urgent care centers are permitted to provide emergency services, then urgent care centers in that state that are geographically separate and distinct from a hospital would fall within the definition of independent freestanding emergency department for purposes of these interim final rules. In contrast, if state licensure of urgent care centers does not permit such facilities to provide emergency services as defined in these interim final rules, then urgent care centers in that state would not be treated as independent freestanding emergency departments for purposes of these interim final rules. Finally, the definition of emergency services also includes additional post-stabilization services, as discussed in section III.B.1.ii of this preamble.

The term “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in EMTALA, including (1) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (2) serious impairment to bodily functions, or (3) serious dysfunction of any bodily organ or part.²⁷ This definition includes mental health conditions and substance use disorders.

The Departments are aware that some plans and issuers currently deny coverage of certain services provided in the emergency department of a hospital

by determining whether an episode of care involves an emergency medical condition based solely on final diagnosis codes, such as International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) codes. In addition, some plans and issuers might automatically deny coverage based on a list of final diagnosis codes initially, without regard to the individual’s presenting symptoms or any additional review. Following an initial denial, plans and issuers might then provide for complete consideration of the claim, and apply the prudent layperson standard, only as part of an appeals process if the participant, beneficiary, or enrollee appeals. These practices are inconsistent with the emergency services requirements of the No Surprises Act and the ACA.²⁸ This is true even if the process for complete consideration of the claim following an initial denial is not designated as a formal appeal. Instead, the determination of whether the prudent layperson standard is met must be made on a case-by-case basis before an initial denial of an emergency services claim.

These interim final rules make clear that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services without limiting what constitutes an emergency medical condition (as defined in these interim final rules) solely on the basis of diagnosis codes. When a plan or issuer denies coverage, in whole or in part, for a claim for payment of a service rendered in the emergency department of a hospital or independent freestanding emergency department, including services rendered during observation or surgical services, the determination of whether the prudent layperson standard has been met must be based on all pertinent documentation and be focused on the presenting symptoms (and not solely on the final diagnosis). This determination must take into account that the legal standard

²⁸ See also *Am. Coll. of Emergency Physicians v. Blue Cross & Blue Shield of Georgia*, No. 20–11511, 2020 WL 6165852 (11th Cir. Oct. 22, 2020) (per curiam) (reversing dismissal of plaintiffs’ ACA and ERISA claims alleging defendants violated prudent layperson standard where review process was based upon physician review of medical records and diagnostic codes; prudent layperson standard ignores a patient’s final diagnosis and instead asks whether a person with average medical knowledge would reasonably think they need emergency services to address their symptoms).

²⁵ 42 CFR 489.24(a)(1)(ii); 68 FR 53221–53264 (Sept. 9, 2003); 73 FR 48654–48668 (Aug. 19, 2008).

²⁶ Association of State and Territorial Health Officials. As Urgent Care Centers Increase, Licensing Authority Falling Under State Health Agencies, (Oct. 11, 2018) available at <https://www.astho.org/StatePublicHealth/As-Urgent-Care-Centers-Increase-Licensing-Authority-Falling-Under-State-Health-Agencies/10-11-18/>.

²⁷ See 42 U.S.C. 1395dd(e)(1)(A).

regarding the decision to seek emergency services is based on whether a prudent layperson (rather than a medical professional) would reasonably consider the situation to be an emergency.²⁹ In covering emergency services, plans and issuers must also ensure that they do not restrict the coverage of emergency services by imposing a time limit between the onset of symptoms and the presentation of the participant, beneficiary, or enrollee at the emergency department. Similarly, plans and issuers also may not restrict the coverage of emergency services because the patient did not experience a sudden onset of the condition.

The Departments are also aware that some plans and issuers that generally provide coverage for emergency services have nonetheless denied benefits for such services based on other general plan exclusions. For example, the Departments are aware of some plans and issuers denying claims for emergency services provided to dependent women who are pregnant, based on a general plan exclusion for dependent maternity care. As explained previously, both the coverage of emergency services rules issued under section 2719A of the PHS Act and the new emergency services requirements included in these interim final rules provide, in part, that if a plan or issuer provides or covers any benefits with respect to services in an emergency department of a hospital (or under these interim final rules, in an independent freestanding emergency department), emergency services must be provided “without regard to any other term or condition of the plan or coverage (other than the exclusion or coordination of benefits . . .).” The Departments clarify that this provision does not permit plans and issuers to exclude benefits for items and services that would otherwise constitute benefits for an emergency medical condition as defined under these interim final rules. This provision does not permit plans and issuers that cover emergency services to deny benefits for a participant, beneficiary, or enrollee with an emergency medical condition that receives emergency services, based on a general plan exclusion that would apply to items and services other than emergency services.

ii. Post-Stabilization Services

Under section 9816(a)(3)(C)(ii) of the Code, section 716(a)(3)(C)(ii) of ERISA, and section 2799A–1(a)(3)(C)(ii) of the PHS Act, emergency services include any additional items and services that are covered under a plan or coverage and furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items and services are furnished) after a participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the other emergency services are furnished. Such additional items and services (referred to in this preamble as post-stabilization services) are considered emergency services subject to surprise billing protections unless the conditions enumerated in section 9816(a)(3)(C)(ii)(II)(aa)–(cc) of the Code, section 716(a)(3)(C)(ii)(II)(aa)–(cc) of ERISA, or section 2799A–1(a)(3)(C)(ii)(II)(aa)–(cc) of the PHS Act, as applicable, are met, as well as such other conditions as specified by the Departments under paragraph (dd) of the respective sections. Therefore, these interim final rules provide that post-stabilization services are emergency services unless all of the following conditions are met.

First, the attending emergency physician or treating provider must determine that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into consideration the individual’s medical condition. The HHS interim final rules codify this requirement at 45 CFR 149.410(b)(1). For this purpose, a treating provider is a physician or health care provider who has evaluated the individual. It is generally expected that a treating provider with medical training and experience related to the individual’s specific medical condition will determine if the individual is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance. This determination is based on all the relevant facts and circumstances and the individual should be involved in the decision-making process, if possible. The determination by the attending emergency physician or treating provider is binding on the facility for purposes of this requirement. This

requirement is based on the Departments’ understanding that such provider is in the best position to make this determination.

For individuals receiving care in or near their plan’s or issuer’s covered service area, as well as individuals with coverage that uses a national network of providers and facilities, the statutory criterion would generally be sufficient to ensure that an individual can freely choose, based on their medical condition, to receive post-stabilization services at a participating facility or participating provider. The additional requirement in these interim final rules that the individual be able to travel to an available participating provider or facility located within a reasonable travel distance, taking into consideration the individual’s medical condition, is necessary and appropriate to carry out the provision of the No Surprises Act, as the requirement is intended to address the common situations in which an individual has received emergency services in a geographic region far from where any participating providers or facilities are located. In cases where the individual cannot travel using nonmedical transportation or nonemergency medical transportation, or cases where there are no participating facilities or participating providers located within a reasonable travel distance, taking into account the individual’s medical condition, the Departments are of the view that individuals are unable to provide consent freely and, therefore, balance billing protections continue to apply.

In addition, the Departments recognize that an individual’s transportation options may vary based on the individual’s location, social risk, and other risk factors. In cases of underserved and geographically isolated communities and those with social risk factors related to income and transportation options, individuals may face additional barriers to obtaining post-stabilization services without a disruption in care. For example, individuals may not have the ability to pay for a taxi, may not have access to a car, may not be able to safely take public transit due to their medical condition, or may not have public transit options available. In these cases, the net effect would be the same: The individual would face unreasonable travel burdens that could prevent them from being able to consent freely to a waiver of the otherwise applicable balance billing protections. The Departments expect the attending emergency physician or treating provider to consider such factors when

²⁹ However, nothing in the statute or these interim final rules prevents a plan or issuer from approving coverage for emergency services solely on the basis of diagnosis codes, or from taking diagnostic codes into account when deciding payment for a claim for emergency services, provided a denial of coverage is not based solely on diagnosis codes.

assessing the individual's ability to travel to a participating provider or facility. The Departments seek comment on the definition of "reasonable travel distance" and whether specific standards or examples should be provided regarding what constitutes an unreasonable travel burden. For example, should reasonable travel distance take into account only mileage, or also other factors, such as traffic or other route conditions that might make traveling difficult, time consuming, or hazardous?

In contrast to situations where a participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation following stabilization, in the event that the individual requires medical transportation to travel, including transportation by either ground or air ambulance vehicle, the individual is not in a condition to receive notice or provide consent. Therefore, the surprise billing protections continue to apply to post-stabilization services provided in connection with the visit for which the individual received emergency services.

Second, the provider or facility furnishing post-stabilization services must satisfy the notice and consent criteria of section 2799B–2(d) of the PHS Act with respect to such items and services (which are implemented in HHS-only interim final rules at 45 CFR 149.410(b)(2), and incorporate by reference the criteria for notice and consent in 45 CFR 149.420(c) through (g)).

Third, the individual (or the individual's authorized representative) must be in a condition to receive the information in the notice described in section 2799B–2 of the PHS Act (which is also implemented in 45 CFR 149.410(b)(3)) and to provide informed consent under such section, in accordance with applicable state law. Whether an individual is in a condition to receive the information in the notice is determined by the attending physician or treating provider using appropriate medical judgment. It is generally expected that an attending physician or treating provider with medical training and experience related to the individual's specific medical condition will make this determination based on all the relevant facts and circumstances. In addition to applying any requirements under state law, such medical professionals should apply the same principles as they would when determining if a patient is able to provide informed consent for

treatment.³⁰ They should assess whether an individual is capable of understanding the information provided in the notice and the implications of consenting. Consideration must be given to the individual's state of mind after receiving the emergency services and the individual's emotional state at the time of consent. For example, consideration must be given to the effect of any alcohol or drug use by the individual, including the use or administration of prescribed medications, as well as to any pain the individual is experiencing, and the impact of those factors on the patient's state of mind. If the individual is experiencing a mental or behavioral health episode or displaying symptoms of a mental or behavioral health disorder, or is impaired by a substance abuse disorder, consideration should also be given as to whether the individual's condition impairs their ability to receive the information in the notice and provide informed consent. In addition, consideration must be given to cultural and contextual factors that may affect the informed decision-making and consent process for members of underserved communities, including lack of trust arising from historical inequities, misinformation about the informed consent process, or barriers to comprehension of the information given through the informed consent process and after the informed consent document is signed.³¹ These barriers may include accessibility, language, and literacy barriers. In addition, the informed consent must be obtained in a way that adheres to all civil rights protections cited within this rulemaking, ensuring that all individuals including those from underserved, underrepresented communities, with limited English proficiency, and with disabilities, are

³⁰ Ethics guidance for physicians, published by the American Medical Association, states that physicians should "[a]ssess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision" as part of the process of seeking informed consent. American Medical Association, Code of Medical Ethics Opinion 2.1.1, available at <https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf> (last visited April 5, 2021). See also Gostin, L.O. Public Health Law, 217–218 (2000) (discussing the four elements of the doctrine of informed consent: Information, competency, voluntariness, and specificity).

³¹ For a discussion of strategies to improve informed consent processes for minority communities, see Quinn, S.C., et al. Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys, *Journal of Empirical Research on Human Research Ethics*, 7(5): 44–55 (Dec. 2012).

able to understand and freely make informed decisions.

Consent must be made voluntarily, meaning the individual must be able to consent freely, without undue influence, fraud, or duress. If post-stabilization services must be provided quickly after the emergency services are provided, it may be challenging for the individual or their authorized representative to have adequate time to make a clear-minded decision regarding consent. Consent obtained through a threat of restraint or immediacy of the need for treatment is not voluntary. In addition, the emergency physician or treating provider should consider whether the individual has reasonable options regarding post-stabilization services, transport, or service provider or facility. The Departments are of the view that the post-stabilization notice and consent procedures should generally be applied in limited circumstances, where the individual knowingly and purposefully seeks care from a nonparticipating provider or facility (such as deciding to go under the care of a specific provider or facility that the individual is familiar or comfortable with), and that the process should not be permitted to circumvent the consumer protections in the No Surprises Act.

Fourth, the provider or facility must satisfy any additional requirements or prohibitions as may be imposed under applicable state law. These interim final rules include this criterion recognizing that some state laws do not permit exceptions to state balance billing protections, such as allowing individuals to consent to waive protections. Thus, states may impose stricter standards by which post-stabilization services will be exempted from the surprise billing protections under these interim final rules, or states might not permit exceptions at all. This requirement is codified in the HHS interim final rules at 45 CFR 149.410(b)(5).

The No Surprises Act authorizes the Departments to specify other conditions that must be satisfied for post-stabilization services to be excepted from the definition of emergency services for purposes of the No Surprises Act. The Departments solicit comments on the conditions described earlier in this section. The Departments also seek comment on whether there are any additional conditions that would be appropriate to designate under the definition of emergency services, such as conditions relating to coordinating care transitions to participating providers and facilities. The Departments also solicit comments on

what guidelines, beyond state laws regarding informed consent, may be needed to determine when an individual is in a condition to receive the written notice and provide consent. For example, are standards needed to account for individuals who are experiencing severe pain, intoxication, incapacitation, or dementia after being stabilized following an emergency medical condition?

iii. Non-Emergency Services Performed by Nonparticipating Providers at Participating Health Care Facilities

Section 9816(b) of the Code, section 716(b) of ERISA, section 2799A-1(b) of the PHS Act, and these interim final rules, apply surprise billing protections in the case of non-emergency services furnished by nonparticipating providers during a visit by a participant, beneficiary, or enrollee at a participating health care facility, unless the notice and consent requirements, as specified in these interim final rules, have been met.

Specifically, if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers benefits with respect to items and services (other than emergency services to which section 9816(a) of the Code, section 716(a) of ERISA, or section 2799A-1(a) of the PHS Act applies), the plan or issuer must cover such items and services furnished to a participant, beneficiary, or enrollee of the plan or coverage by a nonparticipating provider with respect to a visit at a participating health care facility in accordance with these interim final rules, including the requirements regarding cost sharing, payment amounts, and processes for resolving billing disputes described elsewhere in this preamble.

iv. Health Care Facilities

These interim final rules, consistent with section 9816(b)(2)(A) of the Code, section 716(b)(2)(A) of ERISA, and section 2799A-1(b)(2)(A) of the PHS Act, define a participating health care facility, in the context of non-emergency services, as a health care facility that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. These interim final rules also specify that a single case agreement between a health care facility and a plan or issuer, used to address unique situations in which a participant,

beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement with respect to the particular individual involved. Thus, when non-emergency services are furnished by a nonparticipating provider at a health care facility that has a single case agreement in place with respect to the individual being treated, as opposed to an agreement or contract that would apply to all the plan's or issuer's participants, beneficiaries, or enrollees, those non-emergency services would be subject to the protections described in 26 CFR 54.9816-5T, 29 CFR 2590.716-5, and 45 CFR 149.120, as applicable, and the corresponding requirements on providers at 45 CFR 149.420. The Departments are of the view that it is reasonable that an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual's care to be delivered on an in-network basis. Thus, these interim final rules apply the same protections in this circumstance as would apply at health care facilities that participate in the plan or issuer's network.³² The facility is considered a participating facility only with respect to items and services furnished to the individual whose care is covered by the single case agreement. Similarly, these interim final rules define a participating emergency facility to include a facility that has a single case agreement in place with a plan or issuer with respect to a specific individual's care. The Departments seek comment on this approach.

For this purpose, a health care facility described in the statute is each of the following, in the context of non-emergency services: (1) A hospital (as defined in 1861(e) of the Social Security Act); (2) a hospital outpatient department; (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); or (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

In addition, section 9816(b)(2)(A)(ii)(V) of the Code, section 716(b)(2)(A)(ii)(V) of ERISA, and section 2799A-1(b)(2)(A)(ii)(V) of the PHS Act authorize the Departments to designate additional facilities as health care facilities. The Departments solicit comments on other facilities that would be appropriate to designate as health

care facilities. The Departments are interested in comments identifying types of facilities in which surprise bills frequently arise, and are particularly interested in comments regarding whether urgent care centers or retail clinics should be designated as health care facilities for purposes of these interim final rules.

The Departments recognize that state regulation of urgent care centers varies significantly, as does the type of services they are permitted to provide under state law. Under these interim final rules, emergency services provided at urgent care centers that are licensed in a manner that brings them within the definition of independent freestanding emergency department would be subject to cost-sharing and balance billing protections, among others. However, given significant variation in state law definitions, urgent care centers are not included within the definition of health care facilities, in the context of non-emergency services. Thus, in cases where non-emergency services are furnished at participating urgent care centers by nonparticipating providers, those services would not receive the protections under these interim final rules. However, the Departments are of the view that it is possible that individuals may be using urgent care centers (regardless of how they are licensed) in a similar way to how they use independent freestanding emergency departments, in which case it may be appropriate to designate urgent care centers as health care facilities. The Departments seek comment on the degree to which individuals may be using urgent care centers in a similar way to how they use independent freestanding emergency departments. The Departments seek data on how frequently surprise bills arise in the context of urgent care centers. The Departments also seek comment on whether plans and issuers generally contract separately with urgent care centers and the providers who work at the centers, and how frequently contracting practices result in nonparticipating providers furnishing services at participating urgent care centers. The Departments also seek comment on potential definitions of the term urgent care center.

v. Items and Services Within the Scope of a Visit

In addition to items and services furnished by a provider at the facility, a "visit" to a participating health care facility includes the furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and

³² In contrast, as discussed in section III.B.2.vi of this preamble, these interim final rules do not include negotiated rates under single-case agreements in the methodology for calculating the qualifying payment amount.

postoperative services, regardless of whether the provider furnishing such items or services is at the facility. These services are not limited based on whether the provider furnishing the services is physically located at the facility. For example, if a sample is collected during an individual's hospital visit and sent to an off-site laboratory, the laboratory services would be considered to be part of the individual's visit to a participating health care facility, if laboratory services are covered by the plan or coverage. Similarly, if an individual receives a consultation with a specialist via telemedicine during a visit to a participating hospital, those telemedicine services would be considered part of the individual's visit to a participating health care facility. The statutory definition of "visit" also provides authority for the Departments to specify other items and services. The Departments solicit comments regarding other items and services that would be appropriate to include within the scope of a visit for purposes of these interim final rules.

The No Surprises Act and these interim final rules provide for exceptions to the balance billing prohibitions and cost-sharing requirements if the participant, beneficiary, or enrollee is provided a compliant written notice and consents to receive such services from a nonparticipating provider at a participating health care facility. However, these exceptions do not apply with respect to certain ancillary services (in the context of non-emergency services) and other services under certain conditions, as discussed later in this preamble.

vi. Air Ambulance Services

Section 105 of the No Surprises Act added section 9817 of the Code, section 717 of ERISA, and section 2799A–2 of the PHS Act to address surprise air ambulance bills. These provisions apply in the case of a participant, beneficiary, or enrollee who receives services from a nonparticipating provider of air ambulance services, meaning medical transport by a rotary-wing air ambulance, as defined in 42 CFR 414.605, or fixed-wing air ambulance, as defined in 42 CFR 414.605. These interim final rules apply these provisions where a plan or coverage generally has a network of participating providers and provides or covers any benefits for air ambulance services, even if the plan or coverage does not have in its network any providers of air ambulance services. With respect to air ambulance services furnished by

nonparticipating providers (including inter-facility transports), plans and issuers must comply with the requirements regarding cost sharing, payment amounts, and processes for resolving billing disputes described elsewhere in this preamble, if such services would be covered if provided by a participating provider with respect to such plan or coverage.

2. Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities

i. In General

Under section 9816(a) of the Code, section 716(a) of ERISA, section 2799A–1(a) of the PHS Act, and these interim final rules, if a plan or issuer provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the cost-sharing requirement for such services performed by a nonparticipating provider or nonparticipating emergency facility must not be greater than the requirement that would apply if such services were provided by a participating provider or a participating emergency facility. Additionally, if a plan or issuer provides or covers any benefits for non-emergency items and services furnished by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied certain notice and consent criteria with respect to such items and services, the plan or issuer may not impose a cost-sharing requirement for such items and services that is greater than the cost-sharing requirement that would apply had such items or services been furnished by a participating provider. Similarly, if a plan or issuer provides or covers benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider in such a manner that the cost-sharing requirement with respect to such services must be the same requirement that would apply if such services were provided by a participating provider. For example, if a plan or issuer imposes a 20 percent coinsurance rate for emergency services from participating providers or participating emergency facilities, the plan or issuer may not impose a coinsurance rate on emergency services from nonparticipating providers or facilities that exceeds 20 percent. Stakeholders have reported that network participation rates are low among providers of air ambulance services. In instances where a plan or issuer does not have an established cost-

sharing requirement that applies specifically to participating providers, the plan or issuer must calculate the cost-sharing amount using the generally applicable cost-sharing requirement for the relevant item or service under the plan or coverage.

Under sections 9816(a) and (b) and 9817(a) of the Code, sections 716(a) and (b) and 717(a) of ERISA, sections 2799A–1(a) and (b) and 2799A–2(a) of the PHS Act, and these interim final rules, any cost-sharing payments for emergency services, non-emergency services furnished by a nonparticipating provider in a participating health care facility, and air ambulance services furnished by a nonparticipating provider must be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable), respectively (and these in-network deductibles and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to services furnished by a participating provider or facility.

ii. Cost-Sharing Amount

Section 9816(a)(1)(C)(iii) of the Code, section 716(a)(1)(C)(iii) of ERISA, section 2799A–1(a)(1)(C)(iii) of the PHS Act, and these interim final rules also specify that for emergency services furnished by a nonparticipating emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the statute and in these interim final rules.

The "recognized amount" is: (1) An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the QPA, which under these interim final rules generally is the median of the contracted rates of the plan or issuer for the item or service in the geographic region.

By requiring plans and issuers to calculate the cost-sharing amount using the recognized amount, rather than the

amount the plan or issuer ultimately pays the nonparticipating provider or nonparticipating emergency facility for the furnished items or services, the No Surprises Act and these interim final rules limit the effect of provider-payer disputes about payment amounts on participant, beneficiary, or enrollee cost sharing. Under the statute and these interim final rules, the provider or facility and plan or issuer separately determine the total payment amount for the furnished items or services, but that amount generally does not affect the cost-sharing amount the individual must pay.

The Departments are aware that there may be some instances where a nonparticipating health care provider or facility might bill a plan or issuer for an item or service that is subject to these surprise billing protections in an amount less than the QPA. For example, this might be a relatively common occurrence for items whose patent expires after 2019, in instances where the QPA is based off the median of the contracted rates from 2019. In these instances, assuming the plan or issuer would not pay more than the billed charge, calculating cost sharing based on the QPA would require a participant, beneficiary, or enrollee to pay a higher percentage in cost sharing than if the items or services had been furnished by a participating provider. However, section 9816(a)(1)(C)(ii) of the Code, section 716(a)(1)(C)(ii) of ERISA, and section 2799A–1(a)(1)(C)(ii) of the PHS Act expressly prohibit plans and issuers from applying a cost-sharing requirement that is greater than the requirement that would apply if such services were provided by a participating provider or a participating emergency facility. Therefore, under these interim final rules, in circumstances where a specified state law or All-Payer Model Agreement does not apply to determine the cost-sharing amount, cost sharing must be based on the lesser of the QPA or the amount billed by the provider for the item or service. The different methods for determining the recognized amount are discussed in separate sections of this section III.B.2 of this preamble.

With respect to air ambulance services furnished by nonparticipating providers, the recognized amount is not used for purposes of determining cost sharing. Rather, the statute specifies that the cost-sharing requirement with respect to such services must be the same requirement that would apply if such services were provided by a participating provider, and any coinsurance or deductible must be based on rates that would apply for such

services if they were furnished by a participating provider. These interim final rules require that plans and issuers base any coinsurance and deductible for air ambulance services provided by a nonparticipating provider on the lesser of the QPA or the billed amount. The Departments have concluded that this policy is consistent with the statute's general intent to protect participants, beneficiaries, and enrollees from excessive bills, and to remove the individuals as much as possible from disputes between plans and issuers and providers of air ambulance services. In addition, using the QPA is one method of ensuring that any coinsurance or deductible is based on rates that would apply for the services if they were furnished by a participating provider, given that the QPA is generally based on median contracted rates, as opposed to rates charged by nonparticipating providers, and is one basis used for determining the cost-sharing amount in the context of emergency services and items and services furnished by nonparticipating providers at participating health care facilities.

As discussed in this preamble, the Airline Deregulation Act of 1978 (ADA) broadly preempts state laws that relate to air ambulance providers, and the Departments are unaware of any instances in which an All-Payer Model Agreement or a specified state law might apply. In addition, since an All-Payer Model Agreement or a specified state law would not need to follow an approach based on rates that would apply for such services if they were furnished by a participating provider (for example, Medicare rates could be used instead), it is the Departments' view that Congress did not intend to apply the concept of the recognized amount to nonparticipating providers of air ambulance services. The Departments seek comment on any potential alternate approaches for calculating the cost-sharing amount for air ambulance services furnished by nonparticipating providers of air ambulance services.

iii. Out-of-Network Rate

In addition to establishing requirements related to cost sharing, the No Surprises Act and these interim final rules also establish requirements related to the total amount paid by a plan or issuer for items and services subject to these provisions, referred to as the out-of-network rate. The plan or issuer must make a total payment equal to one of the following amounts, less any cost sharing from the participant, beneficiary, or enrollee: (1) An amount determined by an applicable All-Payer Model

Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; (3) in the absence of an applicable All-Payer Model Agreement or specified state law, if the plan or issuer and the provider or facility have agreed on a payment amount, the agreed on amount; or (4) if none of those three conditions apply, and the parties enter into the IDR process and do not agree on a payment amount before the date when the IDR entity makes a determination of the amount, the amount determined by the IDR entity. These four approaches for determining the out-of-network rate are discussed more fully later in this preamble.

The requirements related to cost sharing and to the out-of-network rate apply when a group health plan or coverage provides or covers benefits for services subject to these provisions. The Departments interpret this to mean that the requirements apply when a plan or issuer provides coverage for such items and services, pursuant to the terms of the plan or coverage, even in cases where an individual has not satisfied their deductible.³³ Because the cost-sharing amount is calculated using the recognized amount (or for air ambulance services the lesser of the QPA or the billed amount) that is calculated separately from the determination of the out-of-network rate, these requirements may result in circumstances where a plan or issuer must make payment prior to an individual meeting their deductible. Specifically, where the surprise billing protections apply, and the out-of-network rate exceeds the amount upon which cost sharing is based, a plan or issuer must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount (the latter of which in this case would equal the recognized amount, or the lesser of the QPA or the billed amount), even in cases where an individual has not satisfied their deductible, as illustrated in the following example.

Example. An individual is enrolled in a high deductible health plan with a \$1,500 deductible and has not yet accumulated any costs towards the deductible at the time the individual receives emergency services at an out-of-network facility. The plan determines that the recognized amount for the services is \$1,000. Because the

³³ Absent the balance billing protections under the No Surprises Act and these interim final rules, the plan or issuer would not generally be expected to make a payment to the provider or facility prior to an individual satisfying the deductible.

individual has not satisfied the deductible, the individual's cost-sharing amount is \$1,000, which accumulates towards the deductible. The out-of-network rate is subsequently determined to be \$1,500. Under the requirements of the statute and these interim final rules, the plan is required to pay the difference between the out-of-network rate and the cost-sharing amount. Therefore, the plan pays \$500 for the emergency services, even though the individual has not satisfied the deductible. The individual's out-of-pocket costs are limited to the amount of cost-sharing originally calculated using the recognized amount (that is, \$1,000).

Although such a payment would generally cause a high deductible health plan to lose its status as a high deductible health plan, the No Surprises Act added section 223(c)(2)(F) to the Code to specify that a plan shall not fail to be treated as a high deductible health plan by reason of providing benefits for medical care in accordance with section 9816 or 9817 of the Code, section 716 or 717 of ERISA, or section 2799A–1 or 2799A–2 of the PHS Act (the provisions added by the No Surprises Act related to surprise medical and air ambulance bills), or any state law providing similar protections to individuals, prior to the satisfaction of the deductible.³⁴

iv. Specified State Law

Under section 9816(a)(3)(I) of the Code, section 716(a)(3)(I) of ERISA, section 2799A–1(a)(3)(I) of the PHS Act, and these interim final rules, a specified state law is a state law that provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage to the extent the state law applies. This includes instances where the Departments have interpreted this term to include state laws where the state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt in to a program established under state law, subject to section 514 of ERISA, for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility. In cases where a specified state law applies, the recognized amount (the amount upon which cost sharing is based) and out-of-network rate for emergency and non-emergency services subject to the surprise billing

protections is calculated based on such specified state law.

In order for a state law to determine the recognized amount or out-of-network rate, any such law must apply to: (1) The plan, issuer, or coverage involved, including where a state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt in, subject to section 514 of ERISA; (2) the nonparticipating provider or nonparticipating emergency facility involved (and in the case of state out-of-network rate laws, the nonparticipating provider of air ambulance services involved); and (3) the item or service involved. In instances where a state law does not satisfy all of these criteria, the state law does not apply to determine the recognized amount or out-of-network rate. For example, where a particular state surprise billing law that governs the recognized amount and out-of-network rate applies to a particular plan or coverage but does not apply to nonparticipating neonatologists, who provide a specified ancillary service under section 2799B–2(b)(2) of the PHS Act, the consumer protections under federal law would determine the recognized amount and out-of-network rate with respect to neonatology services while the state law would apply with respect to other provider specialties covered under that state law. Similarly, where a state's surprise billing laws apply only to health maintenance organizations (HMOs), federal protections against surprise billing would govern with respect to other types of coverage while the state protections would apply to HMOs for purposes of determining the recognized amount and out-of-network rate.

The same definition of “out-of-network rate”—including the reference to specified state laws—applies to air ambulance services as to other services. The Departments note, however, that the ADA states in relevant part: “. . . a State, political subdivision of a State, or political authority of at least 2 States may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier that may provide air transportation under this subpart.”³⁵ Assuming that a provider of air ambulance services is an “air carrier” covered by this provision, as is typical,³⁶ the provision preempts

state laws that would limit the amount of payment that the provider of air ambulance services would otherwise be entitled to receive.³⁷ Given the applicability of the ADA, the Departments are not aware of any state laws that would meet the criteria to set the out-of-network rate for nonparticipating providers of air ambulance services when providing services subject to the protections in the No Surprises Act.

The Departments also seek comment on whether health insurance issuers, health care providers, or health care facilities, in instances where they are not otherwise subject to a specified state law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage, should have an opportunity, for purposes of these interim final rules, to opt in to a program established under state law, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility. The Departments seek comment on whether this approach would allow for more flexibility for state laws to apply when, for example, by their terms, they apply to the health insurance issuer and item and service in question, but not to the provider; whether an issuer, provider, or facility would still be subject to any specified state laws in their “home” state if they opt in to a program established under another state's law; and whether an issuer, provider, or facility should be permitted to opt in on an episodic basis. The Departments are concerned that allowing providers and facilities to opt in to a program established under state law could increase health care prices if providers and facilities selectively opt in to state programs that favor providers and facilities in the determination of the out-of-network rate. The Departments seek comment on the potential impact of expanding the ability to opt in to a state program to providers and facilities. The Departments specifically seek comment from health insurance issuers, health care providers, or health care facilities located within or serving

have such authority under the provisions of 14 CFR part 298. See, e.g., *Scarlett v. Air Methods Corp.*, 922 F.3d 1053 (10th Cir. 2019); *Air Evac EMS v. Cheatham*, 910 F.3d 751 (4th Cir. 2018).

³⁷ See, e.g., *Guardian Flight LLC v. Godfread*, 991 F.3d 916, 921 (8th Cir. 2021) (holding that ADA preempted state law prohibiting out-of-network air ambulance providers from balance billing and requiring them to accept amounts paid by insurers); *Bailey v. Rocky Mountain Holdings, LLC*, 889 F.3d 1259, 1269–72 (11th Cir. 2018) (holding that ADA preempted state law that prohibited air ambulance providers from collecting more than amount specified in fee schedule).

³⁴ See section IV.A.5 of this preamble for a discussion of HHS-only interim final rules addressing catastrophic plans' compliance with these requirements.

³⁵ 49 U.S.C. 41713(b).

³⁶ An air ambulance provider is a covered “air carrier” if it has economic authority from the Department of Transportation to provide interstate air transportation. Most air ambulance providers

underserved and rural communities, and other communities facing a shortage of providers on the impact of these provisions on services, coverage, and payment for and within medically underserved, rural, and urban communities.

a. State Law Interaction With ERISA

Under the general preemption clause of section 514(a) of ERISA, state laws are preempted to the extent that they “relate” to employee benefit plans subject to title I of ERISA. There are, however, a number of exceptions to this broad preemption provision. Section 514(b)(2)(A), referred to as the “savings clause,” provides in pertinent part that “nothing in this title (title I of ERISA) shall be construed to exempt or relieve any person from any law of any State which regulates insurance. . . .” Additionally, the preemption provisions of section 731 of ERISA (implemented in 29 CFR 2590.731(a)) apply so that the requirements of part 7 of ERISA are not to be “construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a ‘requirement’ of a federal standard.” The conference report accompanying the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which applied this preemption standard to state laws with respect to its title I health insurance reform provisions, indicates that this preemption is intended to be the “narrowest” preemption of states’ laws.³⁸ States may therefore continue to apply state law requirements to issuers except to the extent they prevent the application of ERISA requirements. Additionally, states have significant latitude to impose requirements on issuers that are more restrictive than the federal law. State laws that impose comparable or additional requirements on health insurance issuers would generally constitute a “specified state law” notwithstanding section 514 of ERISA and would continue to apply.

While section 514(b)(2)(A) saves from ERISA preemption state laws regulating insurance, section 514(b)(2)(B) of ERISA, referred to as the “deemer clause,” provides that a state law “purporting to regulate insurance” generally cannot deem an employee benefit plan to be an insurance company

(or in the business of insurance) for the purpose of regulating such a plan as an insurance company (section 514(b)(6)(A) creates a partial exception to the deemer clause for employee welfare benefit plans that are also multiple employer welfare arrangements (MEWAs)). Thus, to the extent that a state law has a “reference to” or an impermissible connection with ERISA plans (such as laws that govern the payment of benefits), these laws are preempted, to the extent they apply to self-insured plans sponsored by private employers.³⁹ However, section 514 of ERISA does not prevent states from expanding access to a state program and allowing self-insured, ERISA-covered plans to choose to voluntarily comply with it. For example, the Departments allowed such plans to comply with their obligations for external review under section 2719 of the PHS Act by voluntarily opting in to the state external review process.⁴⁰ Similarly, these interim final rules allow self-insured plans (including non-federal governmental plans) to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)–(d) of the Code, section 716(a)–(d) of ERISA, and section 2799A–1(a)–(d) of the PHS Act. A group health plan that opts in to such a state law must do so for all items and services to which the state law applies. Under these interim final rules, a self-insured plan that has chosen to opt in to a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

b. Examples Involving Specified State Laws

The following examples illustrate how state laws may or may not apply. In each example, assume there is no applicable All-Payer Model Agreement that would determine the recognized amount or out-of-network rate.

Example 1. (i) Facts. A health insurance issuer licensed in State A covers a specific non-emergency service

that is provided to an enrollee by a nonparticipating provider in a participating health care facility, both of which are also licensed in State A. State A has a law that prohibits balance billing for non-emergency services provided to individuals by nonparticipating providers in a participating health care facility, and provides for a method for determining the cost-sharing amount and total amount payable. The state law applies to health insurance issuers and providers licensed in State A. The state law also applies to the type of service provided.

(ii) Conclusion. In this Example 1, State A’s law would apply to determine the recognized amount and the out-of-network rate.

Example 2. (i) Facts. Same facts as Example 1, except that the nonparticipating provider and participating health care facility are located and licensed in State B. State A’s law does not apply to the provider, because the provider is licensed and located in State B.

(ii) Conclusion. In this Example 2, State A’s law would not apply to determine the recognized amount and out-of-network rate. Instead, the lesser of the billed amount or QPA would apply to determine the recognized amount, and either an amount determined through agreement between the provider and issuer or an amount determined by an IDR entity would apply to determine the out-of-network rate.

Example 3. (i) Facts. An individual receives emergency services at a nonparticipating hospital located in State A. The emergency services furnished include post-stabilization services, as described in 26 CFR 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), and 45 CFR 149.110(c)(2)(ii). The individual’s coverage is through a health insurance issuer licensed in State A, and the coverage includes benefits with respect to services in an emergency department of a hospital. State A has a law that prohibits balance billing for emergency services provided to an individual at a nonparticipating hospital located in State A and provides a method for determining the cost-sharing amount and total amount payable in such cases. The law applies to issuers licensed in State A. However, State A’s law has a definition of emergency services that does not include post-stabilization services.

(ii) Conclusion. In this Example 3, State A’s law would apply to determine the cost-sharing amount and out-of-network rate for the emergency services, as defined under State A’s law. State A’s

³⁸ See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

³⁹ See *Gobeille v. Liberty Mutual Ins. Co.* 577 U.S. 312 (2015); *Egelhoff v. Egelhoff*, 532 U.S. 141 (2001).

⁴⁰ See, e.g., Technical Release 2010–01; 76 FR 37208, 37211 fn. 13 (June 24, 2011).

law would not apply for purposes of determining the cost-sharing amount and out-of-network rate for the post-stabilization services. Instead, the lesser of the QPA or billed amount would apply to determine the recognized amount, and either an amount determined through agreement between the hospital and issuer or an amount determined by an IDR entity would apply to determine the out-of-network rate, with respect to post-stabilization services.

Example 4. (i) Facts. A self-insured plan, subject to ERISA, covers a specific non-emergency service that is provided to a participant by a nonparticipating provider in a participating health care facility, both of which are licensed in State A. State A has a law that prohibits balance billing for non-emergency services provided to individuals by nonparticipating providers in a participating health care facility, and provides for a method for determining the cost-sharing amount and total amount payable. The law applies to health insurance issuers and providers licensed in State A, and provides that plans that are not otherwise subject to the law may opt in. The law also applies to the type of service provided. The self-insured plan has opted in.

(ii) Conclusion. In this Example 4, State A's law would apply to determine the recognized amount and the out-of-network rate.

The Departments are of the view that it would be uncommon for laws of more than one state to each apply to the same health insurance issuer, and to the same provider for a particular item or service. Therefore, the Departments do not foresee many instances where there might be a question as to which state's law applies to determine the recognized amount or out-of-network rate. However, in such uncommon scenarios, one approach might be for the states involved to make that decision. Another approach might be that the law enacted by the state in which the service is provided would apply. Yet another approach would be for the QPA to apply to determine the recognized amount, and either a negotiated amount or an amount determined by an IDR entity to apply to determine the out-of-network rate. The Departments seek comment on these and any other approaches for resolving this choice-of-law question. The Departments also seek comment on how states have handled such questions prior to the enactment of the No Surprises Act, should these types of conflicts exist.

The Departments are of the view that Congress intended that where state law provides a method for determining the

total amount payable under a plan or coverage, the state law regarding balance billing would govern, rather than the alternative method for determining the out-of-network rate under the No Surprises Act. The Departments interpret the statutory phrase "a State law that provides for a method for determining the total amount payable under such a plan, coverage, or issuer, respectively" broadly as referring not only to state laws that set a mathematical formula for determining the out-of-network rate, or that set a predetermined amount for an out-of-network item or service. Rather, the Departments interpret that language to also include, for example, state laws that require or permit a plan or issuer and a provider or facility to negotiate, and then to engage in a state arbitration process to determine the out-of-network rate. Such state laws provide a process for determining the total amount payable, and in such instances, the timeframes and processes under such a state law related to negotiations and arbitration would apply, as opposed to the timeframes and IDR process under the No Surprises Act.

In addition, the Departments are of the view that Congress did not intend for the No Surprises Act to preempt provisions in state balance billing laws that address issues beyond how to calculate the cost-sharing amount and out-of-network rate. To the extent state laws do not prevent the application of a federal requirement or prohibition on balance billing, the Departments are of the view that such state laws are consistent with the statutory framework of the No Surprises Act and would not be preempted.⁴¹ This view extends to any state law that provides balance billing protections beyond what these interim final rules provide. In fact, Congress specifically indicated that such state balance billing laws may continue in effect along with the balance billing protections set forth in the statute, by requiring in new section 2799B–3 of the PHS Act that providers must disclose to participants, beneficiaries, and enrollees information about federal balance billing protections, plus any other protections that apply under state law. A more detailed discussion of the disclosure requirements appears in section IV.A.3

⁴¹ Section 731(a) of ERISA and section 2724(a) of the PHS Act. As noted above, the HIPAA conference report indicates that this preemption standard is intended to be the "narrowest" preemption of states' laws. See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

of this preamble, which discusses the provisions codified in 45 CFR 149.430.

v. All-Payer Model Agreements

As described earlier, in instances where an All-Payer Model Agreement is applicable, the recognized amount (the amount upon which cost sharing is based with respect to items and services furnished by nonparticipating emergency facilities, and nonparticipating providers of nonemergency items and services in participating facilities) and the out-of-network rate are determined using the amount that the state approves under the All-Payer Model Agreement for such items or services.

An All-Payer Model Agreement is an agreement between the Centers for Medicare & Medicaid Services (CMS) and a state to test and operate systems of all-payer payment reform for the medical care of residents of the state, under the authority granted under section 1115A the Social Security Act. Under the terms of section 1115A of the Social Security Act, such Agreements may waive specific provisions of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for the purposes of testing the Model. All-Payer Model Agreements can vary significantly by state, including in using different approaches for approving payment amounts for items or services covered by the Agreements. The Departments are of the view that it is important to maximally preserve states' abilities to test all-payer payment reform through these Agreements, including their abilities to do so using varied approaches to setting payment amounts. These interim final rules defer to the state to determine the circumstances under which, and how, it will approve an amount for an item or service under a payment system established by an All-Payer Model Agreement. Participating in an all-payer model governed by an All-Payer Model Agreement may be voluntary or mandatory for a given payer; the system of all-payer payment reform may apply statewide or only in certain regions, such as rural regions; and payments under the system of all-payer payment reform may apply only to certain providers or facilities and certain items and services.⁴² To account

⁴² See, e.g., CMS, Vermont All-Payer ACO Model, (updated Apr. 8, 2020) available at <https://innovation.cms.gov/innovation-models/vermont-all-payer-aco-model>; CMS, Pennsylvania Rural Health Model, (updated Jan. 1, 2021) available at <https://innovation.cms.gov/innovation-models/pa-rural>.

for potential variations among All-Payer Model Agreements, the Departments are proposing to take a similar approach that these interim final rules establish with respect to state laws. Specifically, in order for an All-Payer Model Agreement to determine the recognized amount or out-of-network rate, any such Agreement must apply to the coverage involved; to the nonparticipating provider or nonparticipating emergency facility involved (and in the case of the out-of-network rate, to the nonparticipating provider of air ambulance services involved); and to the item or service involved. In instances where an All-Payer Model Agreement does not satisfy all of these criteria, the Agreement does not apply to determine the recognized amount or out-of-network rate, and, unless a specified state law applies, the recognized amount would be determined by the QPA (or the billed charge if less than the QPA), and the out-of-network rate would be the amount determined through agreement between the provider or facility and plan or issuer or the IDR process.

Under these interim final rules, an All-Payer Model Agreement is treated as applicable to a given provider or facility and plan or issuer if the terms of the Agreement, or any agreements described in that Agreement, are binding upon the provider, facility, plan, or issuer, which may occur through different mechanisms. For example, under the All-Payer Model Agreement for the Maryland Total Cost of Care Model and under the Maryland state all-payer law, all payers (including group health plans and health insurance issuers offering group or individual health insurance coverage) pay the amount determined under the Agreement with respect to hospital services covered by the Agreement.⁴³ However, the Agreement generally does not apply to the amount paid to a provider, such as a physician, who furnishes services at a hospital. In Maryland, therefore, the recognized amount and out-of-network rate would be set by the All-Payer Model Agreement for all plans and issuers for

hospital charges covered under the Agreement. But, the All-Payer Model Agreement would generally not be used to set the recognized amount or out-of-network rate with respect to a nonparticipating provider's charges, unless the All-Payer Model Agreement, or any agreements described in that Agreement, specify the payment amount in a particular instance.

Although under state law plans and issuers in Maryland do not have discretion regarding whether to participate in the all-payer rate setting system under the Maryland Total Cost of Care Model, participation in other state-based models governed by All-Payer Model Agreements is voluntary. For example, under the All-Payer Model Agreement for the Vermont All-Payer Accountable Care Organization (ACO) Model, participation by providers, facilities, group health plans, and health insurance issuers is voluntary.⁴⁴ To the extent that both the provider or facility and plan or issuer has opted to participate in the Vermont All-Payer ACO Model and the Vermont All-Payer Model Agreement, or an agreement described in that Agreement, applies to a specific item or service, then that All-Payer Model Agreement would determine the recognized amount and out-of-network rate. But, for example, if a plan has opted to participate, but the provider furnishing the service has not, then the All-Payer Model Agreement would not be used to determine either the recognized amount or out-of-network rate. Instead, if a state law is applicable, the state law would apply. If no state law is applicable, then the recognized amount would be determined using the QPA,⁴⁵ and the out-of-network rate would be the amount agreed upon by the parties or determined through the IDR process established in the No Surprises Act, as discussed further elsewhere in this preamble.

vi. Methodology for Calculating the Qualifying Payment Amount

The No Surprises Act directs the Departments to establish through rulemaking the methodology that a group health plan or health insurance issuer offering group or individual health insurance coverage must use to determine the qualifying payment amount (QPA). As discussed earlier in this preamble, the No Surprises Act and

these interim final rules require cost-sharing requirements imposed by plans and issuers in connection with emergency services furnished by a nonparticipating emergency facility or nonparticipating provider, or in connection with non-emergency services performed by nonparticipating providers at certain participating facilities to be based on the lesser of the billed charge or the QPA where an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified state law does not apply. In addition, IDR entities are directed by statute to consider the QPA when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility or provider in order to determine the total payment for emergency services furnished by a nonparticipating emergency facility or nonparticipating provider, or non-emergency services performed by nonparticipating providers at certain participating facilities that are items and services subject to the IDR process.

In general, under section 9816(a)(3)(E) of the Code, section 716(a)(3)(E) of ERISA, and section 2799A–1(a)(3)(E) of the PHS Act, for a given item or service, the QPA is the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation. The median contracted rate is determined with respect to all group health plans of the plan sponsor or all group or individual health insurance coverage offered by the health insurance issuer that are offered in the same insurance market, consistent with the methodology established by the Departments.

The No Surprises Act specifies an alternative methodology for determining the QPA in cases where a plan or issuer has insufficient information to calculate a median contracted rate for an item or service. The statute, however, envisions that these alternative methodologies, such as use of a third-party database, will be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region. Consistent with this statutory goal, these interim final rules generally seek to ensure that plans and issuers can meet the sufficient-information standard when determining the QPA and that use of alternative methodologies is minimized wherever possible.

The Departments seek comment on all aspects of the methodology established

health-model; CMS. Maryland Total Cost of Care Model available at <https://innovation.cms.gov/innovation-models/md-tccm>.

⁴³ See CMS. Maryland Total Cost of Care Model, (updated Oct. 22, 2020) available at <https://innovation.cms.gov/innovation-models/md-tccm>. Under Maryland law, hospitals regulated by the Maryland Health Services Cost Review Commission (HSCRC) must charge payers the rates set by HSCRC, and payers, including group health plans and issuers offering individual or group health insurance, must pay the rates set by HSCRC. Maryland Code, Health-General Article §§ 19–212 and 19–219(a)(3) and (b)(2)(i) and Maryland Code, Insurance Article § 15–604.

⁴⁴ <https://innovation.cms.gov/innovation-models/vermont-all-payer-aco-model>.

⁴⁵ See prior explanation regarding the requirement that when the surprise billing protections apply, in the event the billed charge is less than the recognized amount, cost sharing would be based on the billed charge.

in these interim final rules for determining the QPA. In particular, the Departments seek comment on whether there are any considerations or factors that are not sufficiently accounted for in the methodology established in these interim final rules; the impact of the methodology on cost sharing, payment amounts, and provider network participation; and whether there are areas where commenters believe additional rulemaking or guidance is necessary. The Departments also seek comment as to the impact of large consolidated health care systems on contracted rates, and the impact of such contracted rates on prices and the QPA. The Departments are concerned that the contracting practices of such health care systems could inflate the QPA, and seek comment on whether adjustments to the QPA methodology are needed.

a. Median Contracted Rate

These interim final rules establish the methodology that plans and issuers must use to calculate the median of contracted rates. The plan or issuer will generally then apply an inflation adjustment to determine the QPA for items and services furnished in the relevant year.

In general, the median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all plans of the plan sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished, and selecting the middle number. These interim final rules define each of the relevant terms, as discussed in more detail in this section of the preamble.

In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. For example, assume the contracted rates for all plans of a sponsor in the same insurance market for a particular item or service provided by a provider in the same or similar specialty in a specified geographic region are \$475, \$490, and \$510. The median contracted rate for this service is \$490. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. If, in the previous example, there were a fourth contracted rate in the amount of \$515, the median contracted rate would be the average of the two middle amounts (\$490 and \$510), or \$500

(((\$490+\$510)/2)). If the same amount is paid under two or more separate contracts, each contract is counted separately. Thus, in the previous example, if there were a fifth contracted rate also in the amount of \$515, the median contracted rate would be \$510, since there are two contracted rates below that amount (\$475 and \$490) and two contracted rates above that amount (\$515 and \$515).

Contracted Rate

The interim final rules define a “contracted rate” as the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.⁴⁶

The No Surprises Act envisions that each contracted rate for a given item or service be treated as a single data point when calculating a median contracted rate. Therefore, if a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate, if the same rate applies to all providers of such provider group or facility under the single contract. Likewise, the rate negotiated under a contract constitutes a single contracted rate regardless of the number of claims paid at that contracted rate. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider for a given item or service, each unique contracted rate constitutes a single contracted rate for purposes of determining the median contracted rate.⁴⁷ Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single

contracted rate (even if the same amount is paid to other providers under separate contracts).

The Departments understand that some plans or issuers may rent provider networks or otherwise contract with third parties to manage provider networks. In these situations, contracted rates between providers and the entity responsible for managing the provider network on behalf of a plan or issuer would be treated as the plan’s or issuer’s contracted rates for purposes of calculating the QPA. The Departments seek comment on whether additional guidance or special rules are needed regarding how to define a contract in this situation.

The Departments also understand that plans and issuers sometimes enter into special agreements with providers and facilities that generally are not otherwise contracted to participate in any of the networks of the plan or issuer. For example, a plan or issuer may negotiate an ad hoc arrangement with a nonparticipating provider or facility to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances. These interim final rules specify that solely for purposes of the definition of contracted rate, a single case agreement, letter of agreement, or other similar arrangement between a plan or issuer and a provider, facility, or provider of air ambulance services does not constitute a contract, and the rate paid under such an agreement should not be counted among the plan’s or issuer’s contracted rates. The term “contracted rate” refers only to the rate negotiated with providers and facilities that are contracted to participate in any of the networks of the plan or issuer under generally applicable terms of the plan or coverage and excludes rates negotiated with other providers and facilities. The Departments are of the view that this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations.⁴⁸

Insurance Market

In calculating the median contracted rate for a given item or service, the plan

⁴⁶ This definition is substantially similar to the definition of “negotiated rate” used for purposes of the transparency in coverage regulations at 26 CFR 54.9815–2715A1(a)(2)(xvi), 29 CFR 2590.715–2715A1(a)(2)(xvi), and 45 CFR 147.210(a)(2)(xvi).

⁴⁷ If a plan or issuer has a contract with multiple providers, with separate negotiated rates with several subgroups of providers, each unique contracted rate will generally constitute a single contracted rate for purposes of determining the median contracted rate. However, as discussed later in this section of the preamble, these interim final rules specify that if a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable. In such cases, the QPA for the particular item or service would take into account only the contracted rates for the applicable provider specialty, and would disregard other unique contracted rates under the same contract.

⁴⁸ In contrast, as discussed earlier in this preamble, these interim final rules specify that a single case agreement constitutes a contractual relationship for purposes of the definition of participating health care facility and participating emergency facility. The Departments are of the view that it is reasonable that an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual’s care to be delivered on an in-network basis, and therefore, that the balance billing protections should apply.

or issuer must take into account the contracted rates under all group health plans of the sponsor or all group or individual health insurance coverage offered by the issuer that are offered in the same insurance market.⁴⁹ The term “insurance market” for purposes of these interim final rules means one of the following: The individual market, small group market, or large group market (each as defined under section 2791(e) of the PHS Act). The relevant insurance market is determined irrespective of the state. For example, in calculating the QPA for an item or service furnished to an enrollee in individual health insurance coverage, an issuer must take into account the contracted rates with providers or facilities in the applicable geographic region across the issuer’s individual market offerings, inclusive of contracted rates for all individual health insurance coverage offered by the issuer in all states in which the issuer offers coverage in the individual market.

With respect to self-insured group health plans, these interim final rules define the term “insurance market” to mean all self-insured group health plans (other than account-based plans and plans that consist solely of excepted benefits) of the plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the QPA on behalf of the plan. The Departments understand that many self-insured group health plans are administered by entities other than the plan sponsor (such as a third-party administrator contracted by the plan) that would be responsible for calculating the QPA on behalf of the sponsor. To reduce the burden imposed on sponsors of self-insured group health plans, these interim final rules permit sponsors of self-insured group health plans to allow their third-party administrators to determine the QPA for the sponsor by calculating the median contracted rate using the contracted rates recognized by all self-insured group health plans administered by the third-party administrator (not only those of the particular plan sponsor). Under this approach, the Departments anticipate

there will be fewer instances where a self-insured group health plan sponsor will lack sufficient information to calculate a median contracted rate for an item or service.

The Departments seek comment on the definition of insurance market with respect to self-insured group health plans and whether any contractual or other issues may prevent an entity, such as a third-party administrator, from using contracted rates from the different self-insured plans it administers to calculate the QPA for a particular self-insured group health plan. DOL also seeks comment on the ability of self-insured group health plan fiduciaries to monitor the calculation of the QPA by the administering entities for compliance with the applicable requirements (for example, by ensuring the entities are using the correct contracted rates).

The Departments have determined that including rates negotiated under other more limited forms of coverage, such as excepted benefits, short-term, limited-duration insurance, and account-based plans, including health reimbursement arrangements, could skew the calculation of the median contracted rate, and these forms of coverage should not be included in the definition of the applicable insurance market. Furthermore, the definition of “qualifying payment amount” under section 2799A–1(a)(3)(E)(i)(I) of the PHS Act refers to individual health insurance coverage, and the term individual health insurance coverage, as defined under section 2791(b)(5) of the PHS Act, excludes short-term, limited-duration insurance.⁵⁰ Therefore, under these interim final rules, when referring to coverage offered by an issuer within the same insurance market for purposes of determining the QPA, the individual market excludes short-term, limited-duration insurance (as defined in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103). In addition, under these interim final rules, all markets exclude coverage that consists solely of excepted benefits (as described in section 9832 of the Code, section 733 of ERISA, and section 2791 of the PHS Act). While excepted benefits can be offered in the individual or group markets, they are exempt from the federal insurance market reforms,⁵¹ and Congress amended the statutory

exemption for these products to include the additional coverage provisions established under new Part D of title XXVII of the PHS Act.⁵² Account-based plans, including health reimbursement arrangements as described in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), make reimbursements subject to a maximum fixed dollar amount for a period, such that the benefit design of these coverage options makes concepts related to surprise billing and choice of health care professionals inapplicable. Therefore, under these interim final rules, for purposes of calculating the QPA, all group markets similarly exclude coverage provided under account-based plans.

The Departments also clarify that any plan or coverage that is not a “group health plan” or “group or individual health insurance coverage” offered by a “health insurance issuer,” as those terms are defined in the Code, ERISA, and the PHS Act, such as a Medicare Advantage or Medicaid managed care organization plan, must also not be included in any insurance market for purposes of determining the QPA. This approach is consistent with the statutory requirement that the median contracted rate is determined with respect to all “group health plans” of the sponsor or all “group or individual health insurance coverage” offered by a health insurance issuer in the same insurance market.

Same or Similar Item or Service

Section 9816(a)(3)(E) of the Code, section 716(a)(3)(E) of ERISA, section 2799A–1(a)(3)(E) of the PHS Act, and these interim final rules provide that a plan or issuer must calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service. Under the interim final rules, the term “same or similar item or service” means a health care item or service billed under the same service code, or a comparable code under a different procedural code system. Service code means the code that describes an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code. A service code is a unique identifier, typically consisting of a string of numeric digits or alphanumeric characters, that corresponds to a standardized description, which is used

⁴⁹ The term “health insurance issuer” has the meaning given the term in section 2791(b) of the PHS Act, which, in relevant part, defines a health insurance issuer as an entity that is licensed to engage in the business of insurance in a state. Thus, an issuer is the licensed entity and the contracted rates of separate licensees under the same holding company are not taken into account.

⁵⁰ Since short-term, limited duration insurance is not individual health insurance coverage, it is also generally not subject to the federal individual market reforms. *See, e.g.*, 81 FR 75316 at 75317 (Oct. 31, 2016) and 83 FR 38212 at 38213 (Aug. 3, 2018).

⁵¹ Section 9831 of the Code, section 732 of ERISA, and sections 2722 and 2763 of the PHS Act.

⁵² These amendments add the phrase “and Part D” to section 2722(b), (c)(1), (c)(2), and (c)(3) of the PHS Act.

to identify with specificity the item or service that was furnished to a patient. Different codes may be assigned to the same general service on the basis of certain variations in the provider's method or approach, the complexity of the procedure or medical decision-making, and patient acuity level. Payers, providers, and facilities understand these service codes and commonly use them for billing and paying claims (including for both individual items and services, and for items and services provided under a bundled payment arrangement). Thus, defining "same or similar item or service" by service code will make it easier for plans and issuers to calculate the QPA, and for providers and facilities to understand the QPA.

These interim final rules include specific requirements to account for modifiers (when applicable), which are codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed. For example, modifiers include hospital revenue codes, which indicate the department or place in the hospital in which a procedure or treatment is performed, as well as codes indicating whether services or procedures were performed by certain types of providers, such as physician assistants, nurse practitioners, certified registered nurse anesthetists, or assistant surgeons. In addition, modifiers can be used to indicate that the work required to provide a service in a particular instance was significantly greater—or significantly less—than the service typically requires. The Departments are of the view that it is important that the QPA methodology account for modifiers that affect payment rates under contracts with participating providers and facilities.

Under the methodology established in these interim final rules, plans and issuers must calculate separate median contracted rates for CPT code modifiers that distinguish the professional services component ("26") from the technical component ("TC"). This will result in separate median contracted rates being calculated for services when billed by a facility versus a provider. In addition, where a plan's or issuer's contracted rates otherwise vary based on applying a modifier code, the plan or issuer must calculate a separate median contracted rate for each such service code-modifier combination. Modifiers that do not cause contracted rates to vary must not be taken into account when calculating the median contracted rate. These rules are intended to ensure that if a plan or issuer adjusts contracted

rates with participating providers and facilities based on modifier codes, those payment adjustments are appropriately reflected in the median contracted rate.

Provider in the Same or Similar Specialty

These interim final rules specify that if a plan or issuer has contracted rates for a service code that vary based on provider specialty, the median contracted rate is calculated separately for each provider specialty, as applicable. These interim final rules define "provider in the same or similar specialty" as the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice. This definition is intended to provide plans or issuers with the flexibility necessary to calculate the median contracted rate, relying on their contracting practices with participating providers. If a plan's or issuer's usual business practice for identifying a provider's practice specialty differs for contracting purposes and other business needs, the plan or issuer should use the method of identifying the practice specialty that it uses for contracting purposes.

The Departments considered requiring a plan or issuer to calculate separate median contracted rates for every provider specialty, but concluded that this approach would lead to more instances in which the plan or issuer would not have sufficient information to calculate the QPAs using its contracted rates. In addition, the Departments understand that not all plans or issuers vary contracted rates by provider specialty, in which case requiring plans and issuers to calculate separate median contracted rates for each provider specialty would increase the burden associated with calculating the QPA without adding specificity to the QPA. Given that the No Surprises Act generally relies on using contracted rates to determine the QPA, the Departments conclude that plans and issuers should be required to calculate median contracted rates separately by provider specialty only where the plan or issuer otherwise varies its contracted rates based on provider specialty.

With respect to air ambulance services, all providers of air ambulance services (including inter-facility transports) are considered to be a single provider specialty for purposes of these interim final rules. The Departments understand that contracted rates may vary depending on whether the air ambulance services are provided using a fixed-wing or rotary-wing aircraft. However, these distinctions based on vehicle type are accounted for in the

QPA methodology established under these interim final rules through the use of service codes that are specific to fixed-wing or rotary-wing aircraft. Therefore, the Departments anticipate that median contracted rates for fixed-wing and rotary-wing aircraft would be determined separately based on the requirement under these interim final rules that median contracted rates be based on the contracted rates for the same or similar item or service, and concluded that it would be redundant to require plans and issuers to also calculate separate median contracted rates on the basis of vehicle type.

The Departments also understand that hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers. The Departments, however, are of the view that because participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider, they should not be required to pay higher cost-sharing amounts (such as coinsurance or a deductible) solely because the air ambulance provider assigned to them has negotiated higher contracted rates in order to cover its higher costs, or because it has a different revenue model, than other types of air ambulance providers. This approach is consistent with the approach these interim final rules take with respect to facilities, discussed in the following section of this preamble, which also generally does not provide for separate median contracted rates to be calculated based on characteristics of a particular facility. The Departments have concluded that this interpretation is consistent with the statute's intent to protect individuals from surprise medical bills.

Facility of the Same or Similar Facility Type

If a plan or issuer has contracted rates for emergency services that vary based on the type of facility (that is, whether a facility is an emergency department of a hospital or an independent freestanding emergency department), the median contracted rate is calculated separately for each such facility type. Plans and issuers subject to the protections in the No Surprises Act are required to cover emergency services at both types of facilities. However, the Departments are aware that plans and issuers have not typically contracted with independent freestanding emergency departments, which may be a reflection of independent freestanding emergency departments' historical ability (prior to the enactment of the No Surprises Act) to charge higher rates for

services furnished on an out-of-network basis, and to balance bill enrollees when the charges were denied in part or in full.⁵³ The Departments are also aware that there may be appreciable differences in the case-mix and level of patient acuity between these types of facilities.⁵⁴ Therefore, where a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute. The Departments seek comment on this approach, and whether it would be more appropriate for plans and issuers to always calculate separate QPAs for hospital emergency departments and independent freestanding emergency departments regardless of whether the plan or issuer varies the payment rate based on facility type, or whether a plan or issuer should never calculate separate QPAs for hospital emergency departments and independent freestanding emergency departments.

However, these interim final rules do not allow plans or issuers to separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital. Given that participants, beneficiaries, and enrollees with emergency medical conditions typically go (or are taken) to the nearest or most convenient emergency department, the Departments are of the view that, individuals generally should not be required to pay higher cost sharing (such as coinsurance or a deductible) based on features of the emergency facility that may have a bearing on its contracted rate with plans and issuers, but which are unrelated or incidental to the facility's role as a provider of emergency services.

Geographic Regions

Under the No Surprises Act, plans and issuers must calculate the median contracted rate for an item or service using contracted rates for the same or

similar item or service provided in the geographic region in which the item or service is furnished. The No Surprises Act directs the Departments, in consultation with the National Association of Insurance Commissioners (NAIC), to establish through rulemaking the geographic regions to be applied when determining the QPA, taking into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined in section 332 of the PHS Act.⁵⁵

In consulting on the geographic regions to be applied under the No Surprises Act, the NAIC recommended that geographic regions correspond to the applicable rating area used for purposes of the individual market and small group market rating rules under section 2701 of the PHS Act, implemented at 45 CFR 147.102, while allowing states the flexibility to establish alternative geographic regions. However, some states define rating area by county, resulting in large numbers of rating areas in a state, some of which might include very few, if any, facilities and providers. Therefore, adopting the rating area definitions as the standard for geographic regions could lead to a large number of geographic regions for which a plan or issuer would have to calculate separate median contracted rates, a large number of geographic regions without sufficient information, as well as a large number of geographic regions in which the median contracted rate is influenced by outliers.

After consultation with the NAIC, the Departments are establishing geographic regions under these interim final rules that reflect differences in health care costs based on whether care is provided in urban or rural areas. The Departments are of the view that these geographic regions take into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined at section 332 of the PHS Act. The Departments intend to monitor the effect of these geographic regions and periodically update such

regions, as appropriate, taking into account the findings of the report submitted under section 109(a) of the No Surprises Act, which addresses, among other things, access to health care items and services in rural areas and health professional shortage areas.

In defining "geographic regions," the Departments have sought not only to minimize instances in which a plan or issuer lacks sufficient information to calculate the median of contracted rates in any particular geographic region, but also to limit the instances in which a plan or issuer has only the minimum amount of information to meet the sufficient information standard, as discussed later in this preamble. Using larger geographic regions, for which plans and issuers are likely to have more information, is expected to reduce the likelihood that the median of contracted rates would be skewed by contracts under which the parties have agreed to particularly high or low payment amounts.

Under these interim final rules, for items and services other than air ambulance services, a geographic region is generally defined as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state. The delineations for MSAs are described by the U.S. Office of Management and Budget (OMB) and published by the U.S. Census Bureau.⁵⁶ MSAs encompass at least one urbanized area with a population of 50,000 or more people, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. MSAs are always established along county boundaries, but may include counties from more than one state. Under this definition, MSAs that cross state boundaries are divided between the respective states, with all the counties in a particular MSA in each state counted as a geographic region.

However, under this definition, if a plan or issuer does not have sufficient information to calculate the median of contracted rates for an item or service provided in an MSA, the plan or issuer must consider all MSAs in the state to be a single region when calculating the median of contracted rates for the item

⁵³ See Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, ch. 8, Stand-alone Emergency Departments, June 2017, available at http://www.medpac.gov/docs/default-source/reports/jun17_ch8.pdf (last visited June 19, 2021).

⁵⁴ See *id.*

⁵⁵ Under section 332 of the PHS Act, a health professional shortage area is (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary of HHS determines has a health manpower shortage and which is not reasonably accessible to an adequately served area, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 254g of title 42 shall be automatically designated as having such a shortage.

⁵⁶ OMB Bulletin No. 20-01. "Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas" (Mar. 6, 2020), available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>. U.S. Census Bureau, Delineation Files, available at <https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html>.

or service provided in that MSA. In such cases, all MSAs in the state will constitute one geographic region, and all other portions of the state will continue to constitute a different region. If after applying these broader regions, a plan or issuer continues to have insufficient information to calculate the median of contracted rates, geographic regions will be based on Census divisions, with one region consisting of all MSAs in the Census division, and one region consisting of all other portions of the Census division. There are nine Census divisions, as published by the U.S. Census Bureau.⁵⁷ This approach will help to reduce instances in which a plan or issuer cannot rely on its own contracted rates to determine the QPA in cases where the plan or issuer is not limited to operating within a single state but instead has provider contracts in a multi-state region.

These interim final rules establish alternate geographic regions with respect to air ambulance services. Given the nature of air ambulance services, the infrequency with which they are provided relative to the other types of items and services subject to the No Surprises Act, and the lower prevalence of participating providers of air ambulance services, the Departments have determined not to apply a definition of geographic regions based on MSAs, as narrow regions would result in more instances of insufficient information.

Thus, for air ambulance services, a geographic region means one region consisting of all MSAs in the state, and one region consisting of all other portions of the state. If a plan or issuer does not have sufficient information to calculate the median of the contracted rates for an air ambulance service using that definition of a geographic region, these interim final rules apply broader regions based on Census divisions—that is, one region consisting of all MSAs in each Census division and one region consisting of all other portions of the Census division. Because air ambulance services can be furnished over large distances, these interim final rules provide that the geographic region to be applied for air ambulance services is determined based on the point of pick-up, meaning the location of the individual at the time the individual is placed on board the air ambulance. This approach is generally consistent with prevailing market practices among both private and public payers.

⁵⁷ U.S. Department of Commerce Economics and Statistics Administration, U.S. Census Bureau, available at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.

Non-Fee-for-Service Contractual Arrangements

The No Surprises Act provides that rulemaking to establish the methodology used to determine the QPA must take into account payments that are made by a plan or issuer that are not on a fee-for-service basis. The Departments are aware that many types of alternative reimbursement models exist that are not standard fee-for-service arrangements. For example, under a bundled payment arrangement, plans and issuers may reimburse a provider for multiple items and services under a single billing code. Other payers have capitation arrangements, under which a provider or panel of providers is paid a fixed amount per member per month.

The Departments understand that when a plan or issuer has a fully- or partially-capitated payment arrangement, the plan or issuer also typically has an internal methodology used to value claims for those payments made on a capitated basis. For example, a plan or issuer with capitation arrangements may have an underlying fee schedule that is used to calculate an individual's cost sharing. The Departments are of the view that, when a plan or issuer has an underlying fee schedule used to determine cost sharing under non-fee-for-service contracts, it is reasonable for the plan or issuer to use the same methodology to assign a value to the item or service for purposes of determining the QPA. This approach is used by plans and issuers in other similar contexts, including when providing data for the risk adjustment program⁵⁸ and when making publicly available in-network rates under the transparency in coverage regulations.⁵⁹

Therefore, in the case of these alternative payment models, such as bundled and fully or partially capitated arrangements, where payment made by a plan or issuer is not fully on a fee-for-service basis, these interim final rules provide that the plan or issuer must calculate a median contracted rate for each item or service using the

⁵⁸ See 45 CFR 153.710(c) (requiring an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a state in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business to derive the costs of all applicable provider encounters using its principal internal methodology for purposes of pricing those encounters).

⁵⁹ See 26 CFR 54.9815–2715A3(b)(1)(C); 29 CFR 2590.715–2715A3(b)(1)(C); 45 CFR 147.212(b)(1)(C) (requiring plans and issuers that use underlying fee schedule rates for calculating cost sharing to make publicly available on an internet website the underlying fee schedule rates for all covered items and services).

underlying fee schedule rates for the relevant items and services, if underlying fee schedule rates are available. The term “underlying fee schedule rate” means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.⁶⁰ If there is no underlying fee schedule rate for an item or service, these interim final rules provide that the plan or issuer must calculate the median contracted rate using a derived amount, which, consistent with the definition in the transparency in coverage regulations, is the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c).

The Departments considered alternative approaches to account for non-fee-for-service contractual arrangements, such as requiring plans and issuers to calculate median contracted rates for service bundles, or allowing plans or issuers to disregard certain types of non-fee-for-service contracts for purposes of calculating the median contracted rate. However, the approach specified in these interim final rules will ensure that the median contracted rate calculation accounts for a range of different contractual arrangements, including instances where a plan or issuer uses different types of contracting models with different providers and facilities. Using an underlying fee schedule or derived amount will allow plans or issuers to, in essence, convert each of their non-fee-for-service contracts into fee-for-service arrangements for purposes of calculating the median contracted rate. By avoiding instances where plans or issuers might have been required to disregard some of their contracts, this approach minimizes the number of instances in which a plan or issuer would not have sufficient information to calculate a median contracted rate and ensures that arrangements that pay for value over service volume are reflected in the QPA. In addition, this approach will result in the calculation of a QPA that aligns with a service code (or service-code modifier

⁶⁰ This definition is substantially similar to the definition of “underlying fee schedule rate” in the transparency in coverage regulations at 26 CFR 54.9815–2715A1(a)(2)(xxii), 29 CFR 2590.715–2715A1(a)(2)(xxii), and 45 CFR 147.210(a)(2)(xxii).

combination). The Departments anticipate this result will be helpful to nonparticipating providers and facilities in understanding how much cost sharing they are permitted to charge for a given item or service, and as they negotiate with the plan or issuer to determine the out-of-network rate.

It is the Departments' understanding that under certain capitated and bundled payment arrangements, providers' payments may be reconciled retrospectively to account for utilization, value adjustments, or other weighting factors that can affect the final payment to a provider. In addition, payers and providers may agree to certain incentive payments during the contracting process to promote the provision of higher-quality, lower-cost health care to participants, beneficiaries, or enrollees over time. These interim final rules specify that when calculating median contracted rates, plans and issuers must exclude risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments. The Departments are of the view that excluding these payments and payment adjustments from the median contracted rates used to determine cost sharing for items and services furnished by nonparticipating providers or facilities is consistent with how cost sharing is typically calculated for in-network items and services, where the cost-sharing amount is customarily determined at or near the time an item or service is furnished, and is not subject to adjustment based on changes in the amount ultimately paid to the provider or facility as a result of any incentives or reconciliation process.

b. Indexing

The No Surprises Act provides that, in instances when the median contracted rate is determined as of January 31, 2019, the QPA for items and services furnished during 2022 is calculated by increasing the median contracted rate by the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) over 2019, the percentage increase over 2020, and the percentage increase over 2021. The No Surprises Act further provides that the QPA for 2022 is then adjusted annually for items and services furnished during 2023 or a subsequent year. Therefore, the increase for any year is the CPI-U for the year, as so defined, divided by the CPI-U for the prior year. The combined percentage increase for 2019, 2020, and 2021 to determine the amount for 2022 is the product of the CPI-U increases for 2019, 2020, and 2021 multiplied together. For any year, the factor will be the quotient

of CPI-U for the current year divided by the CPI-U for the prior year. For example, for an item or service provided in 2023, the 2023 QPA is the 2022 QPA multiplied by the CPI-U 2022/CPI-U 2021.

These interim final rules provide specifications for calculating the percentage increase in CPI-U to ensure that all plans and issuers adjust the percentage in a uniform manner. In order to ensure that uniformity, these interim final rules provide that plans and issuers will calculate the increases using the factors determined by the Treasury Department and the IRS, and published in guidance by the IRS. In determining the factors, these interim final rules provide that the percentage increase for any year is calculated by using the CPI-U published by the Bureau of Labor Statistics of the DOL. For this purpose, the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places. This allows the Departments to provide the percentage increase factor before January 1 of each applicable year with sufficient time to adjust the QPAs for the year.

c. Special Rules for Unit-Based Services

These interim final rules provide special rules for calculating the QPA for items or services for which a plan or issuer generally determines the reimbursement level for the same or similar items or services by multiplying the contracted rate by another unit, such as time or mileage. In these cases, indexing the median contracted rate to calculate the QPA would result in an amount that does not reflect the other units that are generally considered when calculating the in-network payment amount. Therefore, when reimbursement levels are determined using this approach, these interim final rules specify that the QPA is calculated by determining the median contracted rate used for that item or service, indexing that median amount in accordance with the otherwise applicable rules regarding indexing, and then applying the pertinent multipliers. These interim final rules also include specific instructions for calculating the QPA for anesthesia services and for certain service codes for air ambulance services.

Anesthesia Services

Payers generally calculate payment amounts for anesthesia services by multiplying the negotiated rate for the anesthesia conversion factor that has been negotiated between the payer and

the provider (expressed in dollars per unit) by (1) the base unit for the anesthesia service code, (2) the time unit, and (3) the physical status modifier unit. The base unit, time unit, and physical status modifier unit are specific to the individual receiving the anesthesia services. These units are not expressed in dollars per unit, nor do they vary by contract. The base units for an anesthesia service code are the American Society of Anesthesiologists Relative Value Guide base units for that service code. The time unit represents the length of time during which the anesthesia services were furnished, and for purposes of the QPA methodology, is measured in 15-minute increments or a fraction thereof. The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between the various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

These interim final rules include a methodology for calculating the QPA for these anesthesiology services that reflects the manner in which providers are generally paid for these services. To calculate the QPA for anesthesia services furnished during 2022, these interim final rules require the plan or issuer to, first, take the median contracted rate for the anesthesia conversion factor (determined in accordance with the methodology for calculating median contracted rates for service code-modifier combinations) for the same or similar item or service as of January 31, 2019, and increase that amount to account for changes in the CPI-U, using the methodology described earlier in this section of the preamble. This amount is referred to as the indexed median contract rate. The plan or issuer must then multiply this indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit (using the value specified in the most recently published edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide), time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the QPA.

To calculate the QPA for anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must use the indexed median contracted rate for the anesthesia conversion factor, and adjust that amount by the percentage increase in the CPI-U over the previous year using the methodology described earlier in this section of the preamble.

The plan or issuer must then multiply that amount by the sum of the base unit (using the value specified in the most recently published edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide), time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the QPA.

Air Ambulance Services

Payers often reimburse for air ambulance services in part by using air mileage service codes (A0435 and A0436) and reimbursement levels that reflect the number of miles an individual is transported by the air ambulance, which are referred to as loaded miles. Payment amounts are calculated by multiplying the negotiated rate for the service code, referred to in this rule as the air mileage rate, by the number of loaded miles. These interim final rules include a methodology for calculating the QPA for these air mileage service codes that reflects the manner in which providers are generally paid for the service codes.

To calculate the QPA for the portion of air ambulance services billed using the air mileage service codes that are furnished during 2022, the plan or issuer must first increase the median contracted rate, in accordance with 26 CFR 54.9816–6T(c)(1)(i), 29 CFR 2590.716–6(c)(1)(i), or 45 CFR 149.140(c)(1)(i), as applicable. This amount is referred to as the indexed median air mileage rate. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the QPA.

To calculate the QPA for air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must increase the indexed median air mileage rate, determined for such services furnished in the immediately preceding year, using the methodology described in 26 CFR 54.9816–6T(c)(1)(ii), 29 CFR 2590.716–6(c)(1)(ii), or 45 CFR 149.140(c)(1)(ii), as applicable. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the QPA.

d. Cases With Insufficient Information

Section 9816(a)(3)(E)(iii) of the Code, section 716(a)(3)(E)(iii) of ERISA, and section 2799A–1(a)(3)(E)(iii) of the PHS

Act, as added by the No Surprises Act, specify an alternative process to determine the QPA in cases where a group health plan or health insurance issuer offering group or individual health insurance coverage lacks sufficient information to calculate the median of contracted rates in 2019, as well as for newly covered items or services in the first coverage year after 2019.

Definition of Sufficient Information

Under these interim final rules, a plan or issuer is considered to have sufficient information to calculate the median of contracted rates if the plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with the methodology in these interim final rules. In the Departments' view, while a median contracted rate could be calculated with a smaller number of contracts, requiring a minimum of three contracted rates is supported by the statute's direction to calculate a median, rather than a mean. Furthermore, the Departments have determined that three contracted rates for a particular item or service in a geographic region represents the minimum number of contracts necessary to reasonably reflect typical market negotiations while reducing the potential for outlier rates to unduly influence the calculation of the QPA.

Under section 9816(a)(3)(E)(iii) of the Code, section 716(a)(3)(E)(iii) of ERISA, section 2799A–1(a)(3)(E)(iii) of the PHS Act, and these interim final rules, where a plan or issuer that initially does not have sufficient information to calculate the median contracted rate based on January 31, 2019 contracted rates (or for new plans and coverage or new service codes, as discussed in more detail in this section of the preamble) later gains sufficient information, the plan or issuer must calculate the QPA using the median contracted rate for the first sufficient information year. The first sufficient information year is defined as: (1) In the case of an item or service for which a plan or issuer does not have sufficient information to calculate the median of contracted rates in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year after 2022; and (2) in the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates in the year immediately preceding that first year.

In cases in which contracted rates for a year after 2019 must be used to calculate the median contracted rate, a plan or issuer will be considered to have sufficient information to calculate the median contracted rate for a year if, with respect to that year, both of the following conditions are met: (1) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with the methodology in these interim final rules; and (2) the contracted rates account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

The requirement that a plan or issuer have at least three contracted rates for a particular item or service in a geographic region is the same as the requirement that applies when determining whether there is sufficient information to calculate a median contracted rate for items and services furnished during 2022 using the median of contracted rates as of January 31, 2019. The 25 percent minimum claims volume requirement, however, applies where only contracted rates for years after 2019 are used to determine whether a plan or issuer has sufficient information to calculate the median contracted rate in the first sufficient information year. While the Departments are not concerned about manipulation of the QPA in the majority of cases where the median contracted rate is based on 2019 contracted rates, the Departments recognize the potential for plans and issuers to engage in selective contracting practices that artificially change the median contracted rate in cases where subsequent year contracted rates are used to determine the QPA. Therefore, this requirement will help to ensure that when contracted rates for years after 2019 are used to calculate a median contracted rate, those network contracts represent a reasonable proportion of a plan's or issuer's total claims and are not designed to manipulate the QPA.

Eligible Databases

In cases in which a plan or issuer does not have "sufficient information" to calculate a median contracted rate, the No Surprises Act directs the plan or issuer to determine the QPA through use of any database that is determined, in accordance with rulemaking issued by the Departments, to not have any

conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for relevant services furnished in the applicable geographic region (such as a state all-payer claims database).

These interim final rules establish standards for databases, referred to as eligible databases, that may be used to determine the QPA. State all-payer claims databases are categorically eligible under these interim final rules because they are specifically identified as not having any conflicts of interest and as having sufficient information reflecting allowed amounts in section 9816(a)(3)(E)(iii)(I) of the Code, section 716(a)(3)(E)(iii)(I) of ERISA, and section 2799–1(a)(3)(E)(iii)(I) of the PHS Act. Other third-party databases may also be eligible, provided all of the following conditions are satisfied.

First, the database or the organization maintaining the database cannot be affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services, or any member of the same controlled group as, or under common control with, any such entity. For example, if a majority of the members on the governing board of a database or the organization maintaining the database are associated with a health insurance issuer, the database would be considered to have a conflict of interest under these interim final rules, since it is controlled by the issuer. As another example, if an issuer owns 40 percent of the stock of the organization that maintains a database, and its subsidiary owns an additional 20 percent of the stock of the organization that maintains the database, the database would be considered to have a conflict of interest under these interim final rules, since it is effectively controlled by the issuer. As a third example, if an issuer and the organization that maintains a database are both subsidiaries of the same parent organization, the database would be considered to have a conflict of interest under these interim final rules, since it is affiliated with the issuer. In the Departments' view, this standard is critical to ensuring the independence of any database used to determine the QPA. The Departments solicit comment on whether a database should not be affiliated with, or owned or controlled by, other entities, such as plan sponsors or third-party administrators, in order to avoid a conflict of interest. The Departments also seek comment on whether to establish a specific threshold that a party's minority ownership interest must meet or exceed in order to

create a conflict of interest for purposes of these interim final rules.

For purposes of applying the controlled group rules to eligible databases, a controlled group means a group of two or more persons that is treated as a single employer under Code sections 52(a), 52(b), 414(m), or 414(o). The Treasury Department and the IRS are considering whether further guidance is needed under section 52(a) or (b) of the Code to address either organizations exempt from tax under section 501(a) of the Code or nonprofit organizations that, although not exempt from tax under section 501(a) of the Code, do not have members or shareholders that are entitled to receive distributions of the organization's income or assets (including upon dissolution) or that otherwise retain equity interests similar to those generally held by owners of for-profit entities. Until further guidance is issued, those two types of organizations may either rely on a reasonable, good-faith application of section 52(a) and (b) of the Code (taking into account the reasons for which the controlled group rules are incorporated into the definition of eligible database) or apply the rules set forth in 26 CFR 1.414(c)–5(a) through (d) (but substituting “more than 50 percent” in place of “at least 80 percent” each place it appears in 26 CFR 1.414(c)–5).

Second, the database must have sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region. The Departments recognize that for a database to be used to calculate the QPA, the database should contain sufficient data to reflect the true market dynamics in a given geographic region. However, in order to provide flexibility in the initial implementation of the No Surprises Act, these interim final rules do not establish a specific definition of when a database is considered to have sufficient information. The Departments seek comment on how to define when a database has sufficient information, including whether to establish specific criteria that a claims database would need to satisfy in order to demonstrate that it has sufficient information reflecting in-network payment amounts for providers or facilities in the applicable geographic region, such as a requirement that the database represents a specified minimum percentage of the claims volume for the region.

Third, the database must have the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act),⁶¹ and the Children's Health Insurance Program under title XXI of the Social Security Act.

To calculate the QPA for an item or service furnished during 2022 (or in the case of newly covered items or services, in the first coverage year) using an eligible database, the plan or issuer must first identify the rate in the database that is equal to the median of the in-network allowed amounts for the same or similar item or service in the geographic region in the year immediately preceding the year in which the item or service is furnished (or in the case of a newly covered item or service, the year immediately preceding the first coverage year). It is the Departments' view that in-network allowed amounts for items and services are a reasonable proxy for contracted rates, and that where there is insufficient information to calculate the QPA based on the median of a plan's or issuer's own contracted rates, using the median of in-network allowed amounts for all private payers in an eligible database is a reasonable method for approximating the median contracted rate for items and services in the applicable geographic region. The Departments are also of the view that determining the QPA for an item or service using the median of in-network allowed amounts for the same or similar item or service in the geographic region in the year immediately preceding the year in which the item or service is furnished is reasonably likely to result in levels of cost sharing that are

⁶¹ Under section 1115 of the Social Security Act, the Secretary of HHS has the authority to approve experimental, pilot, or demonstration projects that, in his judgment, are likely to assist in promoting the objectives of the Medicaid statute. Under section 1115 authority, the Secretary may waive compliance with certain provisions of Medicaid and CHIP law and may authorize federal matching funds for state expenditures that would not otherwise be federally matchable under the Medicaid and CHIP statutes. Many states have section 1115 demonstrations under which they cover services that would not otherwise be covered under the Medicaid or CHIP programs.

generally in line with the cost-sharing liability incurred by participants, beneficiaries, and enrollees in plans with similar levels of in-network cost-sharing for the same or similar items or services.

Once the median in-network allowed amount has been identified, that rate is then increased by the percentage increase in the CPI-U over the previous year using the methodology described earlier in this section of the preamble. For each subsequent year before the first sufficient information year, the plan or issuer must increase the QPA applicable to items or services furnished in the immediately preceding year by the percentage increase in CPI-U over the preceding year. Plans and issuers must continue to use this methodology until the first sufficient information year, at which point the plan or issuer must calculate the median contracted rate and determine the QPA using the standard methodology discussed earlier in this section of the preamble.

These interim final rules require that plans and issuers use a consistent methodology when relying on an eligible database. Specifically, for any particular item or service, a plan or issuer using a database must use the same database to determine the QPA for that item or service through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).⁶² This consistency requirement is designed to ensure that when relying on an eligible database to determine the QPA for an item or service, a plan or issuer cannot vary the database selected due to the rates associated with that item or service. The Departments seek comment on this consistency requirement and whether additional standards or guidance are needed to ensure compliance and prevent abuse.

Finally, these interim final rules codify section 9816(d) of Code, section 716(d) of ERISA, and section 2799A-1(d) of PHS Act, as added by the No Surprises Act, which provide that a plan or issuer that uses an eligible database to determine the QPA by reason of having insufficient information is responsible for any costs associated with accessing such database. The Departments solicit comment on ways

to help ensure that plans and issuers are charged only reasonable costs for accessing such databases and that entities that provide eligible databases are transparent about their fees and fee structures associated with this process.

New Plans and Coverage

The No Surprises Act directs the Departments to establish a methodology for the sponsor of a group health plan or a health insurance issuer that did not offer any plan or coverage in a geographic region in 2019 to determine QPAs for the first year in which the plan or coverage will be offered in the geographic region. For each subsequent year, that amount is increased by the percentage increase in the consumer price index for all urban consumers over the previous year.

The Departments recognize that while a sponsor or issuer may be newly offering coverage in a geographic region, the sponsor or issuer may have sufficient existing provider contracts under other current coverage in the geographic region where an item or service is furnished to calculate the QPA. The Departments clarify that it is not necessary to establish special procedures to calculate the QPA in these situations. Therefore, under these interim final rules, if the plan or issuer newly offering coverage in a geographic region for a year after 2019 otherwise has sufficient information to calculate a median contracted rate in 2019 in the geographic region where the item or service is furnished, the QPA is determined using the standard methodology for calculating median contracted rates discussed earlier in this section of the preamble.

The Departments recognize that the standard methodology would not be available, however, in cases where the plan or issuer does not have sufficient information to calculate a median contracted rate in the geographic region in which the item or service is furnished, such as in situations where the sponsor or issuer did not offer any plan or coverage in 2019. In this case, the plan or issuer must determine the QPA in accordance with the rules applicable to plans or issuers with insufficient information, or for newly covered items and services, including the use of an eligible database, as discussed earlier in this section of the preamble.

For each subsequent year the plan or coverage is offered in the geographic region, the plan or issuer must increase the QPA for items or services furnished in the immediately preceding year by the percentage increase in the CPI-U over the previous year to determine the

QPA for items and services furnished in that year. Under this approach, new plans and coverage that initially do not have sufficient information to calculate a median contracted rate must use a QPA based on information for the first year of coverage from an eligible database indefinitely, updated only by the inflation adjustment. The Departments seek comment on whether the methodology should instead allow new plans and coverage to transition to calculating a QPA using median contracted rates in an applicable first sufficient information year.

New Service Codes

When service codes are created, plans and issuers may be unable to calculate the QPA using the approaches discussed earlier, because neither the plan or issuer nor any eligible databases have sufficient information regarding the new service code. This situation may occur for new service codes when the service codes describe items or services that have not previously been widely furnished. This situation may also occur when service codes are substantially revised, resulting in new service codes or new descriptors for existing service codes that substantially alter the types of services that would be billed using the original service codes. In this case, the plan, issuer, or eligible database may have sufficient information regarding rates for items and services billed under the service code prior to the revision, but that information may no longer reflect the rates associated with the items and services billed under the revised service code. The No Surprises Act does not specify a methodology for calculating the QPA in these circumstances. However, in the Departments' view, it is necessary that these interim final rules establish a methodology that plans and issuers can rely on for calculating QPAs for new service codes during periods of time when no eligible databases would reasonably be expected to have sufficient data to calculate a QPA.

These interim final rules define "new service code" to mean a service code that was created or substantially revised in a year after 2019. In situations in which a plan or issuer is billed for a covered item or service using a new service code, the plan or issuer must first identify a reasonably related service code that existed in the immediately preceding year. For example, a reasonably related service code might be another service code within the same family of codes, or might involve services that represent similar relative value units. This related service code will be used as a benchmark for

⁶² For example, these interim final rules permit a plan or issuer to rely on different state all-payer claims databases, based on the geographic region in which an item or service is furnished, as state all-payer claims databases may not have sufficient data for items and service furnished outside of the state.

determining the QPA for the new service code. The Departments seek comment on whether additional rules are needed regarding how plans and issuers should be required to identify a reasonably related service code, and on whether the Departments should develop a crosswalk methodology to identify related service codes for each new service code.

The Departments are of the view that, although Medicare payment rates may differ substantially from rates paid by plans and issuers, it is reasonable to use Medicare payment rates to approximate the relative cost of two different but reasonably related service codes. Therefore, if CMS has established a payment rate under the Medicare program for an item or service billed under the new service code, the plan or issuer must calculate the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service under the related service code (with both rates disregarding any adjustments for value-based purchasing arrangements that could lead to bonuses or deductions), and multiply that ratio by the QPA for the related service code for the year in which the item or service is furnished.

The Departments recognize that in some cases the Medicare program might not immediately establish a payment rate for items and services billed under a new service code. Therefore, these interim final rules establish a secondary approach to determine the QPA in these situations. Specifically, for items and services billed using a new service code for which Medicare has not established a payment rate, the plan or issuer must calculate the QPA by first calculating the ratio of the rate that the plan or issuer reimburses for an item or service billed under the new service code compared to the rate that the plan or issuer reimburses for an item or service under the related service code (the relativity ratio), and then multiplying the relativity ratio by the QPA for the item or service billed under the related service code. These interim final rules do not specify a particular method that plans and issuers must use to calculate this relativity ratio. However, the Departments expect plans and issuers to use a reasonable method for making the calculation, and seek comment on whether future rulemaking should specify additional requirements for determining the relativity ratio. For example, plans and issuers could be required to calculate the ratio using the medians or means of the contracted rates for each of the two services. However, the Departments recognize

that it may take time for plans and issuers to enter into negotiated rates for new service codes, and therefore the medians or means may change over time. Alternatively, plans and issuers could be required to calculate the relativity ratio using rates from one contract, based on the assumption that negotiated rates within any given contract would generally produce a similar relativity ratio. The Departments are of the view that using rates from two different contracts would not constitute a reasonable method for calculating the relativity ratio, as this approach could introduce into the relativity ratio, variation from factors that are unrelated to the relative cost of furnishing the item or service, such as the negotiating power of the parties to the contract.

Under the methodology in these interim final rules, for items or services furnished in any subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information in the immediately preceding year), the plan or issuer must calculate the QPA by increasing the QPA calculated for the prior year by the percentage increase in CPI-U over the immediately preceding year.

However, for an item or service billed using a new service code, and furnished in the first sufficient information year for such item or service with respect to such plan or coverage, or furnished in the first year for which an eligible database has sufficient information to enable the plan or issuer to calculate the QPA using the processes that generally apply when an issuer or plan has insufficient information, the plan or issuer must calculate the QPA in accordance with 26 CFR 54.9816–6T(c)(3), 29 CFR 2590.716–6(c)(3), or 45 CFR 149.140(c)(3), as applicable. Thus, once the plan or issuer or an eligible database has sufficient information to calculate a QPA, the QPA for a new service code would be calculated using the median contracted rate of the plan or issuer, or the median of the in-network allowed amounts in the eligible database.

The Departments seek comment on any alternate approaches that could be used to determine the QPA for new service codes.

e. Information To Be Shared About the QPA

The No Surprises Act directs the Departments to specify the information that a plan or issuer must share with a nonparticipating provider or nonparticipating emergency facility, as

applicable, when making a determination of a QPA.

The Departments recognize that providers, emergency facilities, and air ambulance providers subject to the surprise billing rules need transparency regarding how the QPA was determined. This information is also important in informing the negotiation process. In addition, IDR entities are directed by statute to consider the QPA when selecting an offer submitted by the parties through the IDR process. Therefore, to decide whether to initiate the IDR process and what offer to submit, a provider, emergency facility, or provider of air ambulance services must know not only the value of the QPA, but also certain information on how it was calculated.

The Departments seek to ensure transparent and meaningful disclosure about the calculation of the QPA while minimizing administrative burdens on plans and issuers. These interim final rules therefore require that plans and issuers make certain disclosures with each initial payment or notice of denial of payment, and that plans and issuers must provide additional information upon request of the provider or facility. This information must be provided in writing, either on paper or electronically, to a nonparticipating provider, emergency facility, or provider of air ambulance services, as applicable, when the QPA serves as the recognized amount.

First, a plan or issuer must provide the QPA for each item or service involved.

Second, a plan or issuer must provide a statement certifying that, based on the determination of the plan or issuer: (1) The QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and (2) each QPA shared with the provider or facility was determined in compliance with the methodology outlined in these interim final rules. These interim final rules require a statement from the plan or issuer that the QPA applies for purposes of the recognized amount so that providers and facilities will understand that the plan or issuer has determined that neither an All-Payer Model Agreement nor a specified state law applies for purposes of calculating a participant's, beneficiary's, or enrollee's cost-sharing liability, but rather that cost-sharing liability has been calculated using the QPA. With respect to air ambulance services, the statement will ensure providers of air ambulance services understand that the QPA, rather than the billed charge, applies for

purposes of calculating the cost-sharing liability, because the plan or issuer has determined that the QPA is lower than the billed charge. The Departments expect that in most if not all cases where the QPA serves as the basis for determining the recognized amount, the federal IDR process will govern any dispute over payment instead of a specified state law or process. Therefore, this notice will also serve to direct providers or facilities to the federal IDR process if the parties cannot agree on an out-of-network rate.

Third, a plan or issuer must provide a statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day open negotiation period does not result in a determination, generally, the provider or facility may initiate the IDR process within 4 days after the end of the open negotiation period. The plan or issuer must also provide contact information, including a telephone number and email address, for the appropriate office or person to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

In addition, upon request of the provider or facility, a plan or issuer must provide, in a timely manner, information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the specific items and services at issue and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount. If a related service code was used to determine the QPA for a new service code, a plan or issuer must provide information to identify which related service code was used. Similarly, if an eligible database was used to determine the QPA, a plan or issuer must provide information to identify which database was used to determine the QPA.

Finally, if applicable upon request, a plan or issuer must provide a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA. Having information about whether the median contracted rate excludes these types of payment adjustments will better inform the open negotiation and IDR process.

The Departments seek comment on these disclosure requirements and on what additional information a plan or issuer should be required to share with a provider or facility about the QPA, either in all cases or upon request. The Departments also seek comment on whether a specific definition or standard is needed to ensure that information provided upon request is disclosed in a timely manner.

f. Audits

The No Surprises Act requires rulemaking to establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved.⁶³

The enforcement responsibilities of HHS and the states with respect to oversight of health insurance issuer compliance with the federal insurance market reforms are set forth in the PHS Act. Pursuant to section 2723(a)(1) of the PHS Act, as amended by the No Surprises Act, states have primary enforcement authority over health insurance issuers regarding the provisions of Parts A and D of title XXVII of the PHS Act. Under this framework, HHS has enforcement authority over issuers in a state if the Secretary of HHS makes a determination that the state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act.⁶⁴

DOL and the Treasury Department generally have primary enforcement authority over private sector employment-based group health plans. The IRS has jurisdiction over certain church plans. HHS also has primary enforcement authority over non-federal governmental plans, such as those sponsored by state and local government employers.⁶⁵ OPM has jurisdiction over FEHB plans, which are federal governmental plans.

The Departments will generally use existing processes to ensure compliance with Code, ERISA, and PHS Act requirements that apply to group health

plans and health insurance issuers, including the provisions added by the No Surprises Act. HHS's enforcement procedures related to the PHS Act federal insurance market reforms are set forth in section 2723 of the PHS Act and 45 CFR 150.101 *et seq.*, including bases for initiating investigations and performing market conduct examinations. Section 504 of ERISA provides DOL with authority to determine whether any person has violated or is about to violate any provision of ERISA or any regulation or order thereunder. The interim final rules include an audit provision establishing that HHS's existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA consistent with these interim final rules. HHS intends to amend its enforcement regulations through future notice and comment rulemaking to reflect the amendments made to the PHS Act by the No Surprises Act. OPM will audit FEHB plans to ensure that such plans are in compliance with the requirement of determining and applying a QPA.

vii. Determination of Out-of-Network Rate in the Absence of a Specified State Law or an Applicable All-Payer Model Agreement

In instances in which a specified state law or All-Payer Model Agreement does not apply for purposes of specifying the out-of-network rate, the out-of-network rate is determined either through agreement between the provider or facility and plan or issuer; or through an IDR process, if agreement cannot be reached and such process is initiated. If the parties agree to an amount of payment prior to the date on which a certified IDR entity makes a determination with respect to such items or services, that agreed upon amount is the out-of-network rate. Otherwise, the out-of-network rate is the amount of payment determined by the certified IDR entity for the items or services.⁶⁶

3. Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial

The No Surprises Act and these interim final rules establish several procedural requirements that apply to group health plans and health insurance issuers to ensure that billing disputes

⁶³ See section 9816(a)(2)(A) of the Code; section 2799A–1(a)(2)(A) of the PHS Act. The DOL and OPM will rely on the existing agency processes to ensure compliance with the No Surprises Act, as discussed in this section of the preamble.

⁶⁴ Section 2723(a)(2) and (b)(1)(A) of the PHS Act. See also 45 CFR 150.203.

⁶⁵ See section 2723(b)(1)(B) of the PHS Act.

⁶⁶ As noted previously, the Departments intend to implement the federal IDR process in future rulemaking.

related to items and services subject to the balance billing protections in the No Surprises Act are resolved in a timely fashion. These include timeframes for: A plan or issuer to send a notice of denial of payment or make an initial payment; the length of any open negotiation period regarding payment; and initiating the IDR process following an open negotiation period. However, those three requirements do not apply under certain circumstances with regard to post-stabilization services or to out-of-network non-emergency services (other than out-of-network air ambulance services) if the provider or facility provided notice to, and received consent from, the participant, beneficiary, or enrollee (or their authorized representative), as discussed later in this preamble.

Therefore, it is critical that a group health plan or health insurance issuer have knowledge of any notice provided and consent given under these interim final rules for items and services that it covers, and that would otherwise be subject to the surprise billing provisions in the statute and these interim final rules. As discussed later in this preamble, the interim final rules issued by HHS in this rulemaking require providers and facilities to notify plans and issuers when the notice and consent criteria have been satisfied. Absent receiving this information, a plan or issuer must assume that the individual has not waived the protections provided in these interim final rules, and must therefore calculate cost sharing, apply cost sharing to deductibles and out-of-pocket limits, and make any payments to providers and facilities before an individual has satisfied the coverage deductible, accordingly. In instances where a plan or issuer does receive this information, it may rely on the provider's or facility's representation as being true and accurate, unless and until the plan or issuer knows or reasonably should know otherwise. Thus, if a provider or facility indicates to a plan or issuer that the notice and consent described in these interim final rules was properly and timely given and received, the plan or issuer may rely on that information and, for example, apply out-of-network cost sharing for the applicable items and services, unless and until the plan or issuer knows or reasonably should know that the notice and consent was not properly and timely given and received. In cases where a plan or issuer believes that notice was not properly and timely given and received, notwithstanding a provider's or facility's assertion to the contrary, the plan or issuer should

apply the cost-sharing and other requirements set forth in these interim final rules and applicable state law by, among other actions, reprocessing any claims that were not processed consistently with those requirements. The plan or issuer may also submit a complaint against the provider or facility as set forth in these interim final rules at 45 CFR 149.450.

Sections 9816(a)(1)(iv)(I) and 9817(a)(3)(A) of the Code, sections 716(a)(1)(iv)(I) and 717(a)(3)(A) of ERISA, sections 2799A–1(a)(1)(iv)(I) and 2799A–2(a)(3)(A) of the PHS Act, and these interim final rules, require plans and issuers to send “an initial payment or notice of denial of payment” not later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services. Given that plans and issuers cannot comply with this requirement unless the plan or issuer first determines that the billed items and services are covered under the plan or coverage, these interim final rules require that the plan or issuer make such determination not later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services.

The Departments specify in these interim final rules that the 30-calendar-day period generally begins on the date the plan or issuer receives the information necessary to decide a claim for payment for such services, commonly known as a “clean claim” under many existing state laws. To the extent feasible, the Departments encourage providers and facilities to include information about whether the surprise billing protections apply to an item or service on the claim form itself. With respect to non-emergency services, HHS requires, under 45 CFR 149.420(i), nonparticipating providers (or the participating facility on behalf of the nonparticipating provider) to timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility. In addition, in all cases, under either 45

CFR 149.410(e) or 45 CFR 149.420(i), providers and facilities must notify the plan or issuer as to whether the requirements for notice and consent have been met when transmitting the bill, either on the bill or in a separate document. The Departments seek comments with recommendations on how HIPAA standard transactions to submit claims could be modified to accommodate the submission of several types of information on the claim itself. Specifically, the Departments seek comment on how HIPAA standard transactions to submit claims could be modified to include whether the surprise billing protections apply to the items and services included on a claim, whether the item or service was furnished during a visit at a participating health care facility, and whether the requirements for notice and consent have been met. The 30-calendar-day initial payment period also does not prohibit payments outside of the 30-calendar-day timeframe for any future adjustments for errors in payment, such as in cases of duplicate bills where providers and plans or issuers reconcile overpayments. The Departments expect that plans and issuers will act reasonably and in good faith when requesting additional information, by providing specific detail to help ensure that the claimant, provider, or facility understands what is required to perfect the claim. The Departments may specify additional standards if the Departments become aware of instances of abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim. The Departments solicit comment on whether any additional standards are necessary to prevent abusive claims payment practices. Under these interim final rules, a notice of denial of payment means, with respect to an item or service for which benefits are subject to the surprise billing protections, a written notice from the plan or issuer to the provider or facility that payment for the item or service will not be made by the plan or coverage and which explains the reason for denial. A notice of denial of payment could be provided, for example, if the item or service is covered but is subject to a deductible greater than the recognized amount.

In the Departments' view, the statute's reference to an “initial” payment does not refer to a first installment. Rather, this initial payment should be an amount that the plan or issuer reasonably intends to be payment in full

based on the relevant facts and circumstances and as required under the terms of the plan or coverage, prior to the beginning of any open negotiations or initiation of the IDR process. In cases where the provider or facility is willing to accept the cost-sharing amount plus the initial payment (or the cost-sharing amount alone, in cases where a denial of payment is sent) as payment in full, this amount will be treated as the out-of-network rate. If plans and issuers make initial payments that providers and facilities are willing to accept (when combined with the cost-sharing amount) as payment in full, the administrative costs of determining the out-of-network amount will be significantly reduced through the avoidance of an open negotiation period and IDR process.

These interim final rules do not require plans and issuers, when making an initial payment to providers or facilities, to make any specific amount of minimum initial payment. However, several state balance billing laws set standards for minimum initial payment amounts. For example, in Washington State, issuers are required to pay an out-of-network provider or facility a commercially reasonable amount, reduced by the applicable cost-sharing amount, within 30 calendar days of receipt of a claim to which the state's balance billing protections apply. Requiring a minimum initial payment amount may help reduce the number of cases that go to arbitration in some states, and could help to reduce the number of cases that go to the federal IDR process established under the No Surprises Act.

The Departments seek comment on whether to set a minimum payment rate or methodology for a minimum initial payment in future rulemaking, and if so, what that rate or methodology should be. For example, a minimum payment rate could be a specific percentage of the Medicare rate, a specific percentage of the plan or issuer's QPA for the item or service, an amount calculated in the same way the plan or issuer typically calculates payment for the specific item or service to nonparticipating providers or facilities, an amount representing the highest amount that would result from applying two or more of these or other methodologies, or any other method. To the extent comments suggest that a percentage of a rate calculated or determined in a specific way would be appropriate, the Departments seek comment regarding an appropriate specific percentage. The Departments also seek comment on whether a minimum payment rate should be defined as a commercially reasonable

rate based on payments for the same or similar services in a similar area, without requiring any specific methodology. In addition, the Departments seek comment regarding the impact of these provisions on underserved and rural communities, and other communities facing a shortage of providers.

The Departments are aware that the timeframes for deciding post-service claims under the claims and appeals rules issued under section 2719 of the PHS Act and the timeframes for sending an initial payment or notice of denial of payment under these final rules may not always align. The Departments seek to minimize confusion about which types of disputes should be resolved through a plan or issuer's internal claims and appeals process instead of the IDR process established by the No Surprises Act.

The ERISA claims procedure regulation requires group health plans to notify a claimant of a benefit determination for post-service claims not later than 30 days after receipt of the claim. A plan can generally extend this period once for up to 15 days for matters beyond the control of the plan, including if the claimant fails to provide information necessary to decide the claim. In such cases, the plan may notify the claimant they provided insufficient information within 30 days, and the plan must give the claimant at least 45 days to provide additional information. After the information is provided, the plan has 15 days to make a determination. Claims that result in an adverse benefit determination (ABD) may be appealed within 180 days following receipt of the notice of the ABD. The requirements of the ERISA claims procedure regulation are incorporated by reference in the internal claims and appeals and external review requirements added by the Affordable Care Act to section 2719 of the PHS Act and, therefore, subject to limited exceptions, apply to all non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets.

If an initial claim submitted is a clean claim, the timeframes for making the relevant determinations would generally be aligned under these interim final rules and the ERISA claims procedure regulation. However, if a claim is submitted without sufficient information to make a benefit determination, under the ERISA claims procedure regulation, the plan would only have 15 days to make a determination once the claim is resubmitted with the additional

information. Yet, under the No Surprises Act and these interim final rules, the plan would have up to 30 calendar days to send a notice of denial of payment or an initial payment to the out-of-network provider from the time the claim is resubmitted with additional information. Consistent with the requirement that plans and issuers provide an initial payment or notice of denial of payment within 30 calendar days of a provider or facility submitting a clean claim, the Departments clarify that while the ERISA claims procedure regulation would require plans to make a benefit determination within 15 days of a claim being resubmitted with additional information, plans and issuers have 30 calendar days (which is an additional 15 days) to make an initial payment to a nonparticipating provider or facility, or send a separate notice of denial of payment.

The Departments note that there is also a significant distinction between an ABD, which may be disputed through a plan's or issuer's claims and appeals process, and a denial of payment or an initial payment that is less than the billed amount under these interim final rules, which may be disputed through the open negotiation process or through the IDR process. In general, when adjudication of a claim results in a participant, beneficiary, or enrollee being personally liable for payment to a provider or facility, this determination may be an ABD that can be disputed through a plan's or issuer's claims and appeals process. Conversely, when: (1) The adjudication of a claim results in a decision that does not affect the amount the participant, beneficiary, or enrollee owes; (2) the dispute only involves payment amounts due from the plan to the provider; and (3) the provider has no recourse against the participant, beneficiary, or enrollee, the decision is not an ABD and the payment dispute may be resolved through the open negotiation or the IDR process. This clarification is consistent with previous guidance included in FAQs related to the ERISA claims procedure regulation, which have explained that with respect to in-network benefits, the regulation does not apply to requests by health care providers for payments due to the provider, rather than due to the claimant, where the provider has no recourse against the claimant for amounts, in whole or in part, not paid by the plan.⁶⁷ The Departments

⁶⁷ See Benefit Claims Procedure Regulation FAQs, Q A–8, available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/benefit-claims-procedure-regulation>; see also Q C–12 (clarifying that failure to make payment in whole

acknowledge that there may be instances where a participant, beneficiary, or enrollee appeals an ABD (such as, a determination of cost-sharing amounts) through the claims and appeals process concurrently with a provider's challenge to a payment amount through the IDR process.

4. Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers

Section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and section 2799A–1(a)(2)(B)(iv) of the PHS Act direct the Departments to establish a process to receive complaints regarding violations of the application of QPA requirements by group health plans and health insurance issuers offering group or individual health coverage. The Departments are of the view that, in order to effectively enforce the No Surprises Act balance billing protections, the complaints process should extend to all of the consumer protection and balance billing requirements as described in these interim final rules that apply to group health plans and health insurance issuers offering group or individual health coverage. As such, these interim final rules establish a process by which the Departments will receive complaints regarding violations by plans and issuers of the requirements under sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A–1 and 2799A–2 of the PHS Act. The Departments seek comment on whether the complaints process should be restricted to the QPA or extended as described in these interim final rules.

The No Surprises Act also adds section 2799B–4(b)(3) of the PHS Act, which directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements under sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act and to respond to such complaints within 60 days. As such, HHS is issuing HHS-only interim final rules to establish a process by which HHS will receive complaints regarding violations of these requirements by health care providers, facilities, and providers of air ambulance services.

For purposes of the complaint processes for plans and issuers, providers, facilities, and providers of air ambulance services, these interim final

rules define a complaint as a written or oral communication that indicates there has been a potential violation by a plan or issuer of sections 9816 or 9817 of the Code, sections 716 or 717 of ERISA, or sections 2799A–1, 2799A–2 of the PHS Act, or a potential violation by a provider, facility, or provider of air ambulance services of sections 2799B–1, 2799B–2, 2799B–3 and 2799B–5 of the PHS Act, whether or not a violation actually occurred. A complainant means any individual, or their authorized representative, who files a complaint as defined in these interim final rules.

The Departments seek to minimize the burden of filing a complaint and seek to require only the information necessary to process the complaint and conduct an investigation if deemed necessary. Therefore, these interim final rules specify that the Departments will consider a complaint to be filed on the date on which the Departments receive an oral or written statement with information about the complaint sufficient to identify the parties involved (including the plan sponsor, if the complaint involves a group health plan), and the action or inaction that is the subject of the complaint. The information may also include the timing of the alleged violation, and the state where the alleged violation occurred. The Departments seek comment on the information needed to file a complaint, and the definitions in this section.

The Departments have considered whether a complaint should be filed within a defined amount of time of the alleged violation. The Departments understand that timely action is necessary to investigate and adjudicate billing matters and therefore considered whether complainants should be required to file a complaint regarding an alleged violation of the requirements in these interim final rules by a plan, issuer, health care provider or provider of air ambulance services within 90 or 180 calendar days after learning of the alleged violation. Without a time requirement for filing a complaint, the Departments may be restricted in directing the complainant to other state or federal resolution processes with timing requirements such as the internal and external claims review process as described in section 2719 of the PHS Act, or an appropriate IDR process as defined in sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A–1 and 2799A–2 of the PHS Act. However, the Departments are of the view that every complaint should be processed and investigated as appropriate to ensure that any necessary enforcement action can be taken. Therefore, these interim final rules do

not include a time period upon which a complaint must be filed. The Departments seek comment on whether a complainant should be required to file a complaint within a given time period and if so within what time period a complaint should be filed for the purpose of this section.

Section 2799B–4 of the PHS Act directs HHS to respond to complaints regarding violations of balance billing protections by health care providers, facilities, and providers of air ambulance services within 60 days of receipt. The Departments are of the view that the timing for responding to complaints regarding plans and issuers should be the same as that for providers to ensure timely resolution. Therefore, upon receiving the information necessary to file a complaint regarding a plan or issuer, the Departments will respond to complainants under section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and section 2799A–1(a)(2)(B)(iv) of the PHS Act no later than 60 business days after the complaint is received. Similarly, HHS will respond to a processed complaint regarding a health care provider, facility, or provider of air ambulance services under section 2799B–4 of the PHS Act no later than 60 business days after the complaint is received.

The response will be by oral or written means, and will acknowledge receipt of the complaint, notify the complainant of their rights and obligations under the complaints process, and describe the next steps of the complaint resolution process. The Departments may also request any additional information needed to process the complaint. The requested information may include an explanation of benefits, processed claims, information about the health care provider, facility, or air ambulance service involved; information about the plan or issuer covering the individual; information to support a determination regarding whether the service was an emergency service or non-emergency service; the summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage or other evidence of coverage the plan or issuer provides to their participant, beneficiary, or enrollee; documents regarding asserted facts in the complaint that are in the possession of or otherwise attainable by the complainant; or any other information the Departments may need to make a determination of facts for an investigation.

HHS may also request additional information to process a complaint under section 2799B–4 of the PHS Act

or in part due to the imposition of cost-sharing requirements is an ABD).

regarding a health care provider, facility, or provider of air ambulance services. This information may include, but is not limited to, the bills or network status of a health care provider, health care facility, or provider of air ambulance services; information regarding the health care plan or health insurance coverage of a participant, beneficiary or enrollee; information to support a determination regarding whether the service was an emergency service or non-emergency service; documents that support the asserted facts in the complaint in the possession of, or otherwise attainable by the complainant; or any other information HHS needs to make a determination of facts for an investigation. The Departments seek comment on additional information that may be required to process a complaint.

The response may be provided directly upon receipt of the complaint, or it may be provided afterwards, though no later than 60 business days after the complaint is received. The next steps of the complaint resolution process may include referring the complainant to another appropriate state or federal resolution process, referring a complainant to the state or federal regulatory authority with enforcement jurisdiction, or initiating an investigation for enforcement action. The Departments will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of such investigations or enforcement actions, including an explanation of the findings, resolution, or any corrective action taken. The Departments will also make reasonable efforts to notify the complainant if the complaint is transferred to another state or Federal regulatory authority. The Departments seek comment on whether a complainant should receive the notification of the outcome of the complaint within a given time period and if so within what time period a complainant should receive the notice for the purpose of this section.

The Departments intend to provide the public with a seamless experience for filing complaints by creating one system to intake all complaints on behalf of all complainants under section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and sections 2799A–1(a)(2)(B)(iv) and 2799B–4 of the PHS Act. The Departments understand that a complainant may not know which Department has enforcement jurisdiction; therefore, the Departments intend to provide one system that will direct complaints to the appropriate Department for processing, investigation, and enforcement action as

necessary. The Departments will release guidance on where the public can file complaints and welcome comments on the operations, protections, user experience, or other facets of this complaint system. The Departments also seek comment on ways to ensure consumers are aware and know how to use this system.

The Departments seek to uphold Executive Order 13985 and all civil rights protections regarding non-discrimination and accessibility, as noted in prior sections. The Departments will make all reasonable efforts to implement a robust complaint process, including but not limited to, acknowledgement of receipt of a complaint, explanations of rights and information requested, explanations of findings, and referrals to other authorities. The Departments will ensure that the complaints process is accessible to all individuals, that communication and language needs are met, and that all individuals are able to understand the options available to them and information required of them. The Departments seek comment from individuals in underserved and rural communities, minority communities, and persons otherwise adversely affected by persistent poverty or inequality on specific barriers to the complaint process and solutions to address these barriers and ensure equitable access to all aspects of the complaint processes.

C. Choice of Health Care Professionals

In the Patient Protections Final Rule, the Departments finalized regulations addressing the provisions in section 2719A of the PHS Act, regarding patient protections related to choice of health care professional and emergency services.⁶⁸ As explained earlier, the No Surprises Act amended section 2719A of the PHS Act to sunset when the new emergency services protections under the No Surprises Act take effect. The provisions of section 2719A of the PHS Act will no longer apply with respect to plan years beginning on or after January 1, 2022.⁶⁹ The No Surprises Act re-codified the patient protections related to choice of health care professional in newly added section 9822 of the Code,

section 722 of ERISA, and section 2799A–7 of the PHS Act.

To reflect these statutory amendments, these interim final rules add a sunset clause to the current patient protection provisions codified in the Patient Protections Final Rule, and re-codify the provisions related to choice of health care professional without substantive change at 26 CFR 54.9822–1T, 29 CFR 2590.722, and 45 CFR 149.310. These interim final rules make minor technical edits to the original provisions for clarity.

The Departments note that, although the substantive requirements of these regulations have not changed, the No Surprises Act extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. The patient protections under section 2719A of the PHS Act apply to only non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. In contrast, the patient protections under the No Surprises Act apply generally to all group health plans and group and individual health insurance coverage, including grandfathered health plans.⁷⁰ Therefore, the requirements regarding patient protections for choice of health care professional under these interim final rules will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022. Until the requirements under section 9822 of the Code, section 722 of ERISA, and section 2799A–7 of the PHS Act and these interim final rules become applicable, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must continue to comply with the applicable requirements under section 2719A of the PHS Act and its implementing regulations.

D. Applicability

These interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage with respect to plan years (in the

⁶⁸ 80 FR 72191 (November 18, 2015).

⁶⁹ Section 2719A(e) of the PHS Act states, “The provisions of this section shall not apply with respect to a group health plan, health insurance issuers, or group or individual health insurance coverage with respect to plan years beginning on or after January 1, 2022.” The Departments interpret subsection (e) to sunset section 2719A for plan years beginning on or after January 1, 2022.

⁷⁰ Section 2719A was added to the PHS Act by the Affordable Care Act. Section 1251 of the Affordable Care Act provides that certain requirements, including those in section 2719A of the PHS Act, do not apply to grandfathered health plans. The No Surprises Act does not include a comparable exception for grandfathered health plans. Furthermore, section 103(d)(2) of the No Surprises Act amends section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protections provisions, including those related to choice of health care professional, apply to grandfathered health plans.

individual market, policy years) beginning on or after January 1, 2022. The term “group health plan” includes both insured and self-insured group health plans. Group health plans include private employment-based group health plans subject to ERISA, non-federal governmental plans (such as plans sponsored by states and local governments) subject to the PHS Act, and church plans subject to the Code. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance coverage as defined at 45 CFR 147.145. In addition, as discussed further in section V of the preamble, under the OPM interim final rules, FEHB carriers must comply with the Departments’ interim final rules, subject to OPM regulation and contract provisions.

The No Surprises Act amended section 1251(a) of the Affordable Care Act to specify that sections 2799A–1, 2799A–2, and 2799A–7 of the PHS Act apply to grandfathered health plans for plan years beginning on or after January 1, 2022. Therefore, these interim final rules apply to grandfathered health plans (as defined in 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140). In addition, these interim final rules apply to certain non-grandfathered health insurance coverage in the individual and small group markets with respect to which CMS has announced it will not take enforcement action with respect to certain specified market requirements even though the coverage is out of compliance with those requirements (sometimes referred to as grandmothers or transitional plans).⁷¹

These interim final rules do not apply to health reimbursement arrangements, or other account-based plans, as described in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), that make reimbursements subject to a maximum fixed dollar amount for a period, as the benefit design of such plans makes concepts related to surprise billing and choice of health care professionals inapplicable.

By statute, certain plans and coverage are not subject to these interim final rules. This includes a plan or coverage

consisting solely of excepted benefits,⁷² as well as short-term, limited-duration insurance. Excepted benefits are described in section 9832 of the Code, section 733 ERISA, and section 2791 of the PHS Act. Under section 2791(b)(5) of the PHS Act, short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is, therefore, exempt from these interim final rules and the statutory provisions the regulations implement. Short-term, limited-duration insurance is defined in regulations at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103.

These interim final rules do not apply to retiree-only plans. ERISA section 732(a) generally provides that part 7 of ERISA—and section 9831(a) of the Code generally provides that chapter 100 of the Code—does not apply to plans with less than two participants who are current employees (including retiree-only plans, which cover less than two participants who are current employees). Title XXVII of the PHS Act, as amended by the Affordable Care Act, no longer contains a parallel provision at section 2721(a) of the PHS Act. However, as explained in prior rulemaking, HHS will not enforce the requirements of title XXVII of the PHS Act with respect to non-federal governmental retiree-only plans and encourages states to adopt a similar approach with respect to health insurance coverage of retiree-only plans.⁷³ HHS intends to continue to follow this same approach, including with respect to the new market reforms established in the No Surprises Act.

These interim final rules are generally applicable to traditional indemnity plans, meaning plans that do not have networks of providers or facilities. However, the Departments recognize that indemnity plans may have unique benefit designs that cause certain provisions of these interim final rules not to be relevant. For example, the requirements regarding balance billing for non-emergency services provided by nonparticipating providers at certain participating facilities would never be triggered if a plan does not have a network of participating facilities. On the other hand, such requirements could be triggered by plans that have participating facilities but do not have participating providers, either for certain provider types or at all. In addition, requirements that are unrelated to whether a plan or coverage has a network of participating providers

or facilities, such as the requirement that emergency services be covered without the need for any prior authorization determination, even if the services are provided on an out-of-network basis, are applicable to traditional indemnity plans.

The Departments seek comment as to whether there are any other plans with unique benefit designs that should be exempt from all or some of these interim final rules.

IV. Overview of Interim Final Rules—Department of Health and Human Services

A. Preventing Surprise Medical Bills

1. In General

In addition to the new provisions applicable to group health plans and health insurance issuers, discussed in section III of this preamble, the No Surprises Act adds a new Part E of title XXVII of the PHS Act establishing requirements applicable to health care providers, facilities, and providers of air ambulance services. Specifically, the No Surprises Act adds new sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act, which protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from balance bills by prohibiting nonparticipating providers, facilities, and providers of air ambulance services from billing or holding liable individuals for an amount that exceeds in-network cost sharing determined in accordance with the balance billing provisions in circumstances where the balance billing provisions apply. This includes: (1) When emergency services are provided by a nonparticipating provider or nonparticipating emergency facility; (2) when non-emergency services are provided by a nonparticipating provider at a participating health care facility; and (3) when air ambulance services are furnished by a nonparticipating provider of air ambulance services.

Under 5 U.S.C. 8902(p), as added by the No Surprises Act, sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act apply to a health care provider, a facility, and a provider of air ambulance services with respect to a covered individual in a health benefits plan offered by a FEHB carrier in the same manner as they apply with respect to a participant, beneficiary, or enrollee in a group health plan or group or individual health insurance coverage offered by a health insurance issuer. These interim final rules apply to a health care provider, a facility, and a provider of air ambulance services in

⁷¹ CMS Insurance Standards Bulletin Series—INFORMATION—Extension of Limited Non-Enforcement Policy through 2022 (January 19, 2021), available at <https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2022.pdf>.

⁷² Section 9831 of the Code, section 9832 of ERISA, and section 2722 of the PHS Act.

⁷³ 75 FR 34537, 34540 (June 17, 2010).

this same manner.⁷⁴ The applicability of these interim final rules with respect to FEHB carriers is discussed in more detail in section V of this preamble.

With respect to post-stabilization services provided by nonparticipating emergency facilities or nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating health care facilities (including off-site nonparticipating providers who furnish items or services that an individual receives as part of a visit to such health care facility), the prohibitions on balance billing do not apply if certain notice is provided to the participant, beneficiary, or enrollee, and the individual acknowledges receipt of the information in the notice and consents to waive the balance billing protections with respect to the nonparticipating emergency facility or nonparticipating providers to which the notice and consent apply. Under the No Surprises Act and these interim final rules, with respect to certain types of non-emergency services furnished by nonparticipating providers in a participating health care facility, the notice and consent provisions do not apply, meaning the prohibitions on balance billing apply without exception.

Given that the statute and these interim final rules authorize HHS to impose civil money penalties on facilities and providers that violate these requirements, nonparticipating providers should take steps necessary to ensure compliance by, among other actions, determining whether a given item or service is being furnished under circumstances that would trigger the surprise billing protections. For example, nonparticipating providers furnishing non-emergency services at a facility must determine whether the facility is a participating health care facility to determine whether balance billing protections apply. Relatedly, nonparticipating providers and nonparticipating emergency facilities will need to timely communicate with plans and issuers regarding when the limitations on cost sharing in these interim final rules do not apply because the notice and consent criteria (described more fully elsewhere in this preamble) have been satisfied. These HHS interim final rules address the steps providers and facilities must take to ensure the balance billing and cost-sharing protections are applied appropriately and consistently with the statute.

⁷⁴ For purposes of these interim final rules, references to participants, beneficiaries, and enrollees should be construed to include covered individuals in a FEHB plan.

HHS also recognizes that compliance with these requirements may require nonparticipating providers and nonparticipating emergency facilities to refrain from billing an individual directly, even in cases that are not subject to these requirements. For example, the protections applicable to non-emergency services provided by a nonparticipating provider in a participating health care facility apply only with respect to services for which benefits are provided or covered by the plan or coverage. A nonparticipating provider may not have the information necessary to determine whether the services are a covered benefit under the plan or coverage. As a result, the nonparticipating provider may need to bill the plan or issuer directly for the services in order to determine whether the protections apply. Otherwise, the provider risks violating the statute and these interim final rules by billing individuals. HHS understands that nonparticipating providers and facilities frequently bill individuals directly for out-of-network services, leaving the individual to submit the bill to the plan or coverage. HHS seeks comment on the impact this change will have on nonparticipating providers and facilities, and on plans and issuers receiving bills from nonparticipating providers and facilities.

In instances where a provider or facility does balance bill a participant, beneficiary, or enrollee for services in violation of the statute and these interim final rules, the Secretary of HHS (the Secretary) may impose civil money penalties in states where HHS is directly enforcing the balance billing provisions with respect to health care providers, facilities, and providers of air ambulance services. However, the statute provides that the Secretary shall waive the penalties with respect to a health care provider, facility, or provider of air ambulance services who does not knowingly violate, and should not have reasonably known it violated, the provisions, with respect to a participant, beneficiary, or enrollee, if such provider or facility, within 30 days of the violation, withdraws the bill that was in violation of such provision and reimburses the health plan or individual, as applicable, in an amount equal to the difference between the amount billed and the amount allowed to be billed under the provision, plus interest, at an interest rate determined by the Secretary. HHS intends to address enforcement of the requirements of the No Surprises Act applicable to health care providers, facilities, and providers of air

ambulance services in future rulemaking.

2. Notice and Consent Exception to Prohibition on Balance Billing

Under the No Surprises Act and these interim final rules, the protections that limit cost sharing and prohibit balance billing do not apply to certain non-emergency services or to certain post-stabilization services provided in the context of emergency care, if the nonparticipating provider or nonparticipating emergency facility furnishing those items or services provides the participant, beneficiary, or enrollee, with notice, the individual acknowledges receipt of the information in the notice, and the individual consents to waive the balance billing protections with respect to the nonparticipating emergency facility or nonparticipating providers named in the notice.

Non-emergency services furnished by a nonparticipating provider at a participating health care facility are exempt from cost sharing protections and balance billing protections when the notice and consent requirements are met. In contrast, the notice and consent exception does not apply to emergency services, other than post-stabilization services, under certain circumstances, or air ambulance services. A nonparticipating provider or nonparticipating emergency facility may obtain notice and consent from the individual in order to balance bill for post-stabilization services only in the case where a participant, beneficiary, or enrollee has received emergency services and that individual's condition has stabilized, and then only if certain additional conditions are met. Such conditions are described later in this preamble and codified at 45 CFR 149.410(b).

If an individual receives a notice, but does not provide (or revokes) consent to waive their balance billing protections, those protections remain in place. A provider or facility may, subject to other state or federal laws, refuse to treat the individual if the individual does not consent.⁷⁵ However, the cost-sharing and balance billing protections applicable to plans, issuers, providers and facilities would apply with respect to any items or services furnished by the provider or facility subsequent to the

⁷⁵ HHS is aware that some providers and facilities charge fees for cancelled appointments. HHS is of the view that an individual cannot provide consent freely if a provider or facility will require the individual to pay a fee if the appointment is cancelled because the individual refuses or revokes consent.

provision of the notice, and absent consent.

The requirements related to the notice and consent exception are set forth in section 2799B–2 of the PHS Act, as added by the No Surprises Act, and implemented at 45 CFR 149.410 and 45 CFR 149.420 of the HHS interim final rules, describing the requirements for post-stabilization services and non-emergency services, respectively. These interim final rules outline the requirements related to the content, method, and timing of the notice and consent communications; requirements related to language access; exceptions to the applicability of the notice and consent process; requirements for the retention of notice and consent documents; and requirements to notify the plan or issuer regarding consent provided by the participant, beneficiary, or enrollee.

i. Standards for Notice

The No Surprises Act and these interim final rules allow an individual to waive balance billing protections only after receiving a written notice that includes detailed information designed to ensure that individuals knowingly accept out-of-pocket charges (including charges associated with balance bills) for care received from a nonparticipating provider or nonparticipating emergency facility. In HHS's view, the option to consent to waive balance billing protections may be valuable to individuals in certain instances where they knowingly and purposefully seek care from a nonparticipating provider. For example, an individual with a complex health condition may want to be treated by a specialist who is not in their plan's network. If that specialist will not treat the individual unless the specialist can bill the individual directly for the care (and balance bill the individual), that individual may want to waive the balance billing protections. HHS seeks comment on striking the appropriate balance between allowing a specialist to refuse to treat an individual unless the specialist can balance bill the individual, while ensuring that the individual is not being pressured into waiving the balance billing protections. In HHS's view, it is important that these consumer protections do not present a barrier to obtaining out-of-network care, when an individual knowingly seeks out such care. However, it is equally important that individuals are not unknowingly subject to balance billing. Therefore, the No Surprises Act and these interim final rules allow an individual to waive balance billing protections in limited circumstances

only, and only if the nonparticipating providers or nonparticipating emergency facility have provided the participant, beneficiary, or enrollee with appropriate notice explaining the applicable consumer protections and the implications of providing consent.

Section 2799B–2(d)(1)(A) of the PHS Act requires providers and facilities to use a written notice specified by HHS in guidance. Therefore, these interim final rules require providers and facilities to provide the notice using the standard notice document provided by HHS in guidance. The standard notice document will contain the elements required by the statute in a manner that is intended to be easy to read and comprehend. The notice must be provided in accordance with guidance issued by HHS. HHS is of the view that requiring use of the standard notice will help to ensure that the notice includes the content that is required to be included in the notice under the No Surprises Act and these interim final rules. Providers and facilities will need to tailor the document in each case to include information specific to the individual (for example, by identifying the provider or facility, as applicable, and adding the good faith estimated amount).

HHS is concerned that individuals may be less likely to review the notice carefully if it is embedded within other information or provided with additional consent forms. Therefore, these interim final rules require that the notice be provided with the consent document, and together these documents be given physically separate from, and not attached to or incorporated into any other documents. Providers and facilities must provide the notice within the required timeframe. The notice must be written and provided on paper, or, as practicable, electronically, as selected by the individual. The notice must meet applicable language access requirements, as described in this HHS interim final rule. A participating health care facility may provide the notice on behalf of the nonparticipating provider.⁷⁶

Authorized Representatives

The notice may be provided to the individual's authorized representative

⁷⁶ However, if a facility that has agreed to provide the notice on behalf of the nonparticipating provider fails to provide the notice and obtain consent, or provides notice and obtains consent in a manner that does not satisfy the regulatory requirements in these interim final rules, the notice and consent criteria would not be considered to be met. Therefore, the cost-sharing and balance billing protections would continue to apply to the items and services furnished by the nonparticipating provider.

instead of the individual, and consent may be provided by the authorized representative on behalf of the individual. These interim final rules specify that for purposes of 45 CFR 149.410 and 149.420, an authorized representative is an individual authorized under state law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. Although treating providers may be authorized under state law to provide consent to treatment, HHS is of the view that providers should generally not be permitted to receive notice or provide consent regarding treatment by a nonparticipating provider or facility because of the strong likelihood of an inherent financial or professional conflict of interest. These same concerns extend to employees of the facility at which the items or services are furnished. HHS is also of the view that these concerns are not warranted for providers or facility employees that are family members of the individual, because of their presumed interest in the well-being of the individual, or providers that are unaffiliated with the provider or facility furnishing the care. HHS is of the view that these limitations provide important consumer protections to ensure that an individual's authorized representative is acting in the individual's best interest rather than the interests of the provider or facility. HHS seeks comment on whether and how the term "family member" should be defined. HHS is sensitive to concerns that some individuals may not have a familial relation formally recognized under applicable state law, or other documented legal partnership with individuals whom they consider family. Therefore, when interpreting this requirement, HHS will construe the term "family member" broadly to include such individuals prior to the issuance of additional guidance.

Timing of Notice

In order to ensure that a participant, beneficiary, enrollee, or authorized representative has an opportunity to properly review and consent to a notice to receive items or services furnished by a nonparticipating provider or nonparticipating emergency facility and waive balance billing protections, the provider or facility must provide such a notice in the timeframe specified in the statute and this interim final rule. As specified in section 2799B–2(d) of the PHS Act, if an individual schedules an

appointment for such items or services at least 72 hours before the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, no later than 72 hours before the date of the appointment; and if an individual schedules an appointment for such items or services within 72 hours of the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, on the day that the appointment is made. In addition, these interim final rules specify that in the situation where an individual is provided the notice on the same day that the items or services are furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply.

This 3-hour requirement is intended to address situations where an individual might be asked to provide consent immediately before a provider furnishes the item or service, which may prevent their consent from being truly voluntary. Stakeholders have recommended that notice and consent procedures be unavailable when an individual visits a participating facility and receives care from a nonparticipating provider from whom the individual did not seek out services (for example, if a specialist furnishes an unexpected consultation on the recommendation of the attending physician). Stakeholders expressed concern that such providers might provide the notice at the time they appear for the consultation, and the individual might feel compelled to consent to receive care. HHS is of the view that the requirement that the notice be provided no later than 3 hours prior to furnishing items or services helps to ensure individuals can voluntarily provide informed consent, while not removing the informed consent option entirely in instances where the appointment is made the same day as the date the services are scheduled. HHS seeks comment on whether such a time limit is a reasonable approach, as well as whether the 3 hours' time requirement should be shorter or longer, in order to best ensure that consent is freely given while also facilitating timely access to care. For example, HHS is interested in understanding if there are situations where this time requirement may unduly delay access to urgently necessary care, including in the post-

stabilization care context.⁷⁷

Alternatively, HHS is interested in understanding if more time may be necessary for an individual to read, understand, and consider their options, including considering whether they can resolve prior authorization or other care management limitations, before voluntarily consenting to treatment. HHS is also interested in whether these timing requirements present barriers to providers' and facilities' ability to comply with the requirement that the notice and consent documents be provided to the individual in paper or, as practicable, electronic form, as selected by the individual.

Content of Notice

As stated previously, a provider or facility must provide the written notice using the form specified by HHS in guidance, customized to include the information specified in 45 CFR 149.420(d) (and 45 CFR 149.410(b)(2), for post-stabilization services, as applicable).

The notice must state that the health care provider furnishing the items or services is a nonparticipating provider, or that the health care facility furnishing the items or services is a nonparticipating emergency facility, as applicable, with respect to the health plan or coverage. The provider or facility will need to customize the form to identify the provider or facility by name. This will help ensure individuals understand for which specific providers or facilities they would be waiving their balance billing protections.

The notice must include the good faith estimated amount that such nonparticipating provider or nonparticipating emergency facility may charge the individual for the items and services involved, including any item or service that the nonparticipating provider reasonably expects to provide in conjunction with such items and services. In the case of a nonparticipating emergency facility, the notice must include the good faith estimate for such items or services that would reasonably be expected to be provided by the nonparticipating emergency facility or by nonparticipating providers as part of the visit at such facility. HHS is including the requirement regarding disclosing

items and services reasonably expected to be provided in order to ensure that the participant, beneficiary, or enrollee has an accurate understanding of the cost of care. As discussed in section IV.A.2.iv of this preamble, individuals cannot waive the balance billing protections for items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished for which the nonparticipating provider or nonparticipating facility satisfied the notice and consent criteria.

Nonparticipating providers who are providing this notice are required to provide a good faith estimate for only the items or services that they would be furnishing and are not required to provide a good faith estimate for items or services furnished by other providers at the facility. However, if a nonparticipating provider has not satisfied the notice and consent criteria, balance billing and cost-sharing protections will apply to the individual with respect to items and services furnished by that nonparticipating provider, even if a different nonparticipating provider has satisfied the notice and consent criteria with respect to the same visit. If they choose, multiple nonparticipating providers that are furnishing related items and services for an individual may provide a single notice to the individual, provided that: (1) Each provider's name is specifically listed on the notice document; (2) each provider includes in the notice a good faith estimate for the items and services they are furnishing, and the notice specifies which provider is providing which items and services within the good faith estimate; and (3) the individual has the option to consent to waive balance billing protections with respect to each provider separately.

HHS is of the view that an individual cannot consent to waive balance billing and cost-sharing protections unless they have been informed of their potential liability with respect to both the facility and provider charges related to receiving post-stabilization services at a nonparticipating emergency facility. Therefore, nonparticipating emergency facilities must include in the written notice the good faith estimated amount that the participant, beneficiary, or enrollee may be charged for items or services furnished by the nonparticipating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or

⁷⁷ A provider or facility is never required to provide notice and seek consent from a participant, beneficiary, or enrollee. To the extent a provider is concerned that the 3 hours' prior requirement will result in a delay in care that is detrimental to the individual, the provider or facility can furnish the items or services, subject to the balance billing protections, rather than providing notice and seeking consent to waive the protections.

services). HHS seeks comment regarding potential challenges nonparticipating emergency facilities may have in coordinating the development of a good faith estimate on behalf of both the facility and providers. To the extent that the nonparticipating facility omits from the good faith estimate information about items and services provided by a nonparticipating provider, the notice and consent criteria will be not be considered met for items and services furnished by that provider, and the requirements in 45 CFR 149.410(a) (and the corresponding requirements on plans and issuers) would apply.

HHS is aware that nonparticipating providers and nonparticipating emergency facilities generally are unable to calculate what an individual's final out-of-pocket costs (inclusive of balance bills) will be for items and services partially or wholly covered by the individual's plan or coverage. Therefore, the good faith estimated amount should reflect the amount the provider or facility expects to charge for furnishing such items or services, even if the provider or facility intends to bill the plan or coverage directly. In calculating this good faith estimated amount, the provider or facility is expected to apply the same process and considerations used to calculate the good faith estimate that is required under section 2799B-6(2) of the PHS Act. HHS seeks comment regarding the method by which this good faith estimated amount should be calculated, and anticipates addressing this requirement in future rulemaking. The notice must make clear that the provision of the good faith estimate in the notice, or the individual's consent to be treated, does not constitute a contract with respect to the charges estimated for such items and services, or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility. HHS seeks comment regarding whether the provider or the facility should be required to include information about what may be covered by the individual's plan or coverage and an estimate of the individual's out-of-pocket costs.

The notice must provide information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility or from the provider. HHS recognizes that there may be challenges for nonparticipating providers or facilities to identify what prior authorization and other care management limitations may apply with respect to a plan or coverage in which they do not participate. Therefore, providers and facilities may provide

general information in order to satisfy this requirement, but to the extent possible, HHS encourages them to contact the issuer or plan about any such limitations so that they can include specific information in the notice. HHS interprets this statutory provision to require information on prior authorization or care management requirements to extend to care furnished by both providers and facilities, in order for participants, beneficiaries, and enrollees to understand all requirements associated with their care before they consent to treatment and balance billing. Requiring that the notice include specificity regarding prior authorization or care management requirements could improve the usefulness of the information to individuals compared to general information about what requirements may apply, but may make providing notices overly burdensome for providers and facilities. HHS seeks comment on whether providers and facilities should instead be required to include in the notice specific information about any prior authorization and care management requirements that apply to any items and services covered under the notice. HHS also seeks comment on barriers or other burdens facing nonparticipating providers or facilities in obtaining this information from a plan or issuer.

The notice must clearly state that the individual is not required to consent to receive such items or services from such nonparticipating provider or nonparticipating emergency facility. The notice must state that the individual may instead seek care from an available participating provider or at a participating emergency facility, with respect to the plan or coverage, as applicable, and that in such cases, in-network cost-sharing amounts will apply.

In cases where post-stabilization services are being furnished by a nonparticipating provider at a participating emergency facility, the notice must include a list of any participating providers at the participating emergency facility who are able to furnish the items or services involved. The notice must inform the individual that they may be referred, at their option, to such a participating provider. HHS seeks comment regarding the format and content of the referral list to be included in the notice, including any challenges that providers may have in providing this information, and any further requirements that should be applied to providers when furnishing this information to the individual.

ii. Standards for Consent

In order to meet the notice and consent requirements of the No Surprises Act and these interim final rules, the nonparticipating provider, participating health care facility on behalf of the nonparticipating provider, or nonparticipating emergency facility must obtain from the participant, beneficiary, or enrollee the individual's acknowledgment that they consent to be treated and balance billed by the nonparticipating emergency facility or nonparticipating provider under circumstances where the individual elects to receive such items or services. The consent must be provided voluntarily, meaning that the individual has consented freely, without undue influence, fraud, or duress. An incomplete consent document will be treated as a lack of consent and balance billing protections will still apply.

As with the notice document, providers and facilities must use the standard consent document specified by HHS in guidance, and the consent document must be provided in accordance with such guidance. The consent document, specified in guidance, contains the information (or fillable fields for the information) required to be included in the consent form under these interim final rules, and described further in this section of the preamble. Providers and facilities will need to tailor the document to include information specific to the individual. In addition, as discussed previously, these interim final rules require that the consent be accompanied by the notice document, and that these documents be given together at the same time, physically separate from and not attached to or incorporated into any other documents. The consent document must be signed (including by electronic signature) by the individual, or the individual's authorized representative.

The nonparticipating provider, participating health care facility on behalf of the nonparticipating provider, or nonparticipating emergency facility must provide the individual with a copy of the signed notice and consent in-person, or through mail or email, as selected by the individual.

The notice and consent documents must meet applicable language access requirements, as described in these interim final rules. The signed consent document must acknowledge that the individual has been provided with the written notice as described in these interim final rules, in the form selected by the individual. The signed consent document must also acknowledge that

the individual has been informed that the payment made by the individual might not accrue toward meeting any limitation that the plan or coverage places on cost sharing, including an explanation that the payment might not apply to an in-network deductible or out-of-pocket maximum under the plan or coverage.

The consent document must state that, by signing the consent document, the individual agrees to be treated by the nonparticipating provider or nonparticipating emergency facility and understands that the individual may be balance billed and subject to cost-sharing requirements that apply to services furnished by nonparticipating providers or nonparticipating emergency facilities. In the case of a nonparticipating provider seeking consent, by signing the consent document, the individual agrees to waive balance billing and cost-sharing protections for only the items or services furnished by the provider or providers specifically named in the notice. In HHS's view, an individual cannot provide informed consent to waive balance billing protections with respect to an unnamed provider, as the individual would not be on notice that the individual may be balance billed for items or services furnished by that provider. In addition, the individual may choose to consent to waive balance billing protections with respect to items or services furnished by none, some, or all of the nonparticipating providers listed in the notice.

The signed consent document must include the date on which the individual received the written notice and the date on which the individual signed such consent to be furnished the items or services covered in the notice. In order to ensure that consent is provided prior to when the item or service is received, HHS also requires that the signed consent document include the time at which the individual signed the consent.

The signed consent provided by the individual constitutes the individual's consent to the receipt of the information contained in the notice document, and includes an acknowledgement that they may be balance billed for the receipt of the items or services. The consent does not constitute a contractual agreement with regard to any estimated charge or amount included in the notice or consent document, or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility. Consent obtained by the provider or facility under this notice and consent process in no way substitutes for or modifies requirements

for informed medical consent otherwise required of the provider or facility, under state law or codes of medical ethics.

The participant, beneficiary, or enrollee may revoke consent by notifying the provider or facility in writing prior to the furnishing of the items or services. If an individual revokes consent, the balance billing protections apply to applicable items or services provided after the revocation as if consent was never provided. HHS is of the view that the option to revoke consent is a critical safeguard to ensure that balance billing protections are waived only when individuals knowingly, purposefully, and freely provide informed consent. HHS seeks comment on whether additional rulemaking or guidance is needed on how an individual can revoke consent.

iii. Language Access

A nonparticipating provider or nonparticipating emergency facility providing a participant, beneficiary, or enrollee, or such individual's authorized representative, with a notice under section 2799B–2(d) of the PHS Act must make the notice available in any of the 15 most common languages in the geographic region in which the applicable facility is located. HHS is of the view that individuals cannot provide meaningful consent if they cannot understand the information provided in the written notice and consent documents. These interim final rules, therefore, also require that the notice and consent document be made available in any of the 15 most common languages in the geographic region in which the applicable facility is located. Providers and facilities will need to translate the standard notice and consent documents specified by HHS in guidance into the applicable 15 languages.

A provider or facility meets this requirement if it provides the notice and consent documents in the 15 most common languages in its state. However, HHS recognizes that in some cases, particularly in larger states or metropolitan areas, these 15 languages may not adequately represent the languages spoken by the population served by the provider or facility.⁷⁸ Therefore, the provider or facility may

alternatively choose to provide the notice and consent documents in the 15 most common languages in its geographic region, which reasonably reflects the geographic region served by the applicable facility. For example, a facility that serves the greater Los Angeles area may choose to provide the notice and consent documents in the 15 most common languages within that geographic region, instead of the 15 most common languages in the state of California.

HHS considered different standards to apply in defining such geographic regions, and is seeking comment regarding the appropriate standard. HHS's objective is to implement a standard that ensures that the language accessibility requirement is responsive to the needs of the individuals served by the provider or facility, while mitigating inconsistencies in the way that such geographic regions are determined. HHS is interested in comments regarding the use of metropolitan statistical areas (MSAs),⁷⁹ hospital service areas (HSAs),⁸⁰ hospital referral regions (HRRs),⁸¹ and public use microdata areas (PUMAs),⁸² applied based on where the applicable facility is located, as well as other standards that may be well-suited for this purpose. HHS also seeks comment on what language access standards would be appropriate in circumstances where the applicable facility serves populations in multiple states.

As noted earlier in this section, HHS is of the view that individuals cannot provide meaningful consent if they cannot understand the information provided in the written notice and consent document. These interim final rules, therefore, add a language access requirement to address circumstances in which the individual cannot understand any of the 15 languages in which the notice and consent document are available. If the individual's preferred language is not among the 15 most common languages in which the documents are made available by the nonparticipating provider or nonparticipating emergency facility, or the individual cannot understand the language in which the notice and consent documents are provided, as self-reported by the individual, the

⁷⁹ <https://www.census.gov/programs-surveys/metro-micro/about.html>.

⁸⁰ <https://www.dartmouthatlas.org/faq/>.

⁸¹ <https://www.dartmouthatlas.org/faq/>.

⁸² [https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20\(PUMAs\)%20are%20non%20overlapping%2C,and%20the%20U.S.%20Virgin%20Islands.](https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20(PUMAs)%20are%20non%20overlapping%2C,and%20the%20U.S.%20Virgin%20Islands.)

⁷⁸ See, e.g., "Understanding Communication and Language Needs of Medicare Beneficiaries" (2017), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf> ("The common languages in a given region, city, or town may vary greatly from those spoken in the state or in the U.S. as a whole.").

notice and consent requirements described in these interim final rules are not met unless the provider or facility furnishes the individual with a qualified interpreter.

The provider or facility should provide the notice and consent documents, or the qualified interpretive services, as applicable, in the individual's self-reported, preferred language. Individuals should be asked what language they prefer to communicate in regarding health care information, for written or verbal communication, as applicable. An individual's preference might not be the same for written and verbal communication, and an individual's preference might not correlate with the individual's native language.

In interpreting the statutory requirements regarding language access in the notice and consent process, HHS recognizes communication, language, and literacy barriers are associated with decreased quality of care, poorer health outcomes, and increased utilization.⁸³ Alternatively, the use of appropriate language services and at appropriate literacy levels in health care settings is associated with increased quality of care, improved patient safety outcomes, and lower utilization of costly medical procedures.⁸⁴ HHS is of the view that it is imperative that health care providers

and facilities take these efforts to provide the required notice and consent information in a manner understandable to the participant, beneficiary, or enrollee, to help achieve the goal of the statute and ensure that individuals are aware their rights and the options available to them.

Providers and facilities are also required to comply with other state and federal laws regarding language access, to the extent applicable. HHS reminds health care providers and facilities that recipients of federal financial assistance must comply with federal civil rights laws that prohibit discrimination. These laws include section 1557 of the Affordable Care Act,⁸⁵ title VI of the Civil Rights Act of 1964,⁸⁶ section 504 of the Rehabilitation Act of 1973,⁸⁷ and the Americans with Disabilities Act of 1990.⁸⁸ Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as written translation of written content in paper or electronic form into languages other than English. Section 1557 and section 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply. Consistent with Executive Order 13985 and civil rights protections cited in these regulations, HHS particularly seeks comments from minority and underserved communities including those with limited English proficiency and those with disabilities who prefer information in alternate and accessible formats, and stakeholders who serve such communities, on whether the provisions and protections related to communication, language, and literacy sufficiently address barriers that exist to ensuring all individuals can read, understand, and consider their options related to notice and consent. HHS also

seeks comment on what additional or alternate policies HHS may consider to help address and remove such barriers.

HHS understands that the technical nature of these protections may inherently pose barriers to individuals or their authorized representatives as they consider their options. Numerous studies have indicated that consumer comprehension of common health insurance concepts is varied and that many are not able to accurately answer questions about their health plan's benefit design or health care costs.⁸⁹ Individuals may also face intersecting and overlapping barriers (commonly referred to as the Social Determinants of Health) as they interact with the health care system, in addition to numerous technical forms and documents as part of receiving care. HHS solicits comment on how to best strike the balance between consumer friendliness and usability of such documents, while ensuring that they are consistent with these interim final rules and the statutory intent. HHS specifically seeks comment from those with experience in supporting individuals with low health literacy, including providers, patient advocates, and navigators, as well as those with experience in user design, in order to ensure that documents conveying these protections and opportunities to convey notice and consent are understandable and accurate.

iv. Exceptions to the Availability of Notice and Consent

The notice and consent exception is not applicable with respect to some non-emergency items or services.⁹⁰ Instead, the prohibition on balance billing and the in-network cost-sharing requirements, as described in these interim final rules, always apply with respect to those items or services. In addition, the exception for notice and consent is not applicable with respect to emergency services, except for post-stabilization services, under certain conditions.

First, as specified in section 2799B–2(b) of the PHS Act, with respect to non-

⁸³ Batencourt, J.R., et al., Improving Patient Safety Systems for Patients with Limited English Proficiency: A Guide for Hospitals, Agency for Healthcare Research and Quality, Publication No. 12–0041, September 2012; Proctor, K. et al., The Limited English Proficient Population: Describing Medicare, Medicaid, and Dual Beneficiaries, Health Equity Vol. 2.1, 2018; Green, A.R. and Nze, C., Language-Based Inequity in Health Care: Who is the “Poor Historian”?, American Medical Association Journal of Ethics, Vol. 19, Number 3: 263–271, March 2017; Shamsi, H. et al., Implications of Language Barriers for Healthcare: A Systematic Review, Oman Medical Journal, Vol. 53, No. 2:e122, 2020; de Moissac, D., Bowen, S., Impact of Language Barriers on Quality of Care and Patient Safety for Official Language Minority Francophones in Canada, Journal of Patient Experience, Vol. 6(1) 24–32, 2019; Napoles, A.N., et al., Inaccurate Language Interpretation and its Clinical Significance in the Medical Encounters of Spanish-speaking Latinos, Med Care. 2015 November; 53(11): 940–947; Divi, C., et al., Language Proficiency and Adverse Events in U.S. Hospitals: a Pilot Study, Int'l Journal for Quality in Health Care, vol. 19, no.2; Ali, P.A. and Watson, R., Language Barriers and their Impact of Provision of Care to Patients with Limited English Proficiency: Nurses Perspective, J. Clin. Nurs., 2018 Mar;27(5–6); Flores G. Language barriers to health care in the United States. N Engl J Med 2006; 355:229–231. Ku L, and Flores G. Pay now or pay later: Providing interpreter services in health care. Health Affairs. 2005;24(2): 435–444; Hampers L.C., et al. Language barriers and resource utilization in a pediatric emergency department. Pediatrics. 1999; 103(6): 1253–1256; Dewalt D.A., et al. Literacy and health outcomes: A systematic review of the literature. J. Gen Intern Med. 2004;19(12):1228–1239. doi:10.1111/j.1525–1497.2004.40153.x.

⁸⁴ *Id.*

⁸⁵ 42 U.S.C. 18116.

⁸⁶ 42 U.S.C. 2000d *et seq.*

⁸⁷ 269 U.S.C. 794.

⁸⁸ 42 U.S.C. 12101 *et seq.*

⁸⁹ <https://www.policygenius.com/blog/health-insurance-literacy-survey-2019/>; <https://www.cmu.edu/dietrich/sds/docs/loewenstein/ConsumerMisUnderstandHealthIns.pdf>.

⁹⁰ 45 CFR 149.420(b) applies in cases of non-emergency services furnished by a nonparticipating provider at a participating facility and not in cases of emergency services. Additionally, 45 CFR 149.410(c) specifies that the notice and consent exception for post-stabilization services does not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time a post-stabilization service is furnished for which the nonparticipating provider or nonparticipating emergency facility already satisfied the notice and consent criteria.

emergency services, the notice and consent exception does not apply to ancillary services, which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner; items and services provided by assistant surgeons, hospitalists, and intensivists; diagnostic services, including radiology and laboratory services; and items and services provided by a nonparticipating provider, only if there is no participating provider who can furnish such item or service at such facility.

Additionally, as specified in section 2799B–2(c) of the PHS Act, the notice and consent exception does not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished for which a nonparticipating provider satisfied the notice and consent criteria. For example, even if an individual has consented to waive balance billing and in-network cost-sharing protections with respect to items and services provided by certain nonparticipating providers related to a knee surgery, that individual has not consented, nor are providers permitted to seek consent under the statute and these interim final rules, to waive those protections with respect to unforeseen, urgent medical needs that arise during the knee surgery. Because individuals lack the requisite information to provide informed consent to waive balance billing and cost-sharing protections with respect to unforeseen, urgent medical needs, HHS has determined that the rationale for the statutory exception for notice and consent to not extend to unforeseen, urgent medical needs with respect to non-emergency services also applies to unforeseen, urgent post-stabilization services. Therefore, these interim final rules provide that any notice provided and consent obtained with regard to the furnishing of certain items or services does not extend to additional items or services furnished in response to unforeseen, urgent medical needs either in the context of a nonparticipating provider in a participating facility, or of post-stabilization services.

The statute authorizes HHS to expand the definition of ancillary services to include items and services provided by other types of providers. HHS seeks comment on other ancillary services that should be considered to be made ineligible for the notice and consent exception. In particular, HHS is interested in comments on whether there are other ancillary services for which individuals are likely to have

little control over the particular provider who furnishes items or services. HHS is of the view that it is with respect to these types of providers that notice and consent procedures are least appropriate. HHS is also interested in comments regarding the types of ancillary services for which surprise bills are most common, and whether they should be added to the definition of ancillary services that are not subject to the notice and consent exception. Finally, HHS seeks comment on what criteria HHS should use in determining whether other ancillary services should be added to the definition.

Furthermore, the statute authorizes HHS to specify a list of advanced diagnostic laboratory tests that would not be considered ancillary services under this definition. Any such advanced diagnostic laboratory tests would still be subject to the surprise billing protections described in these interim final rules, but the notice and consent exemption process would also be available for these tests. HHS seeks comment on what criteria HHS should consider in determining whether an advanced diagnostic laboratory test should be excepted from the definition of ancillary services, and on any specific advanced diagnostic laboratory tests that should be considered to be made eligible for the notice and consent exception.

v. Retention of Certain Documents

Under Section 2799B–2(e) of the PHS Act and these interim final rules, nonparticipating emergency facilities, participating health care facilities, and nonparticipating providers are required to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished. Specifically, when a nonparticipating emergency facility obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, for an item or service furnished to the individual by the facility or any nonparticipating provider at such facility, the facility must retain the written notice and consent for the 7-year period. Similarly, when a participating health care facility obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, for an item or service furnished to the individual by a nonparticipating provider at such facility, the facility must retain the written notice and consent for a 7-year period. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, or

such individual's authorized representative, where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility so that the facility retains the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period. HHS interprets the retention requirement to apply to providers as well as facilities, in order to ensure that all notice and consent documents are appropriately retained, regardless of how they are obtained.

vi. Requirements To Notify the Plan or Issuer

For each item or service furnished by a nonparticipating provider or nonparticipating emergency facility, the provider (or participating facility on behalf of the nonparticipating provider) or nonparticipating emergency facility, as applicable, must timely notify the plan or issuer as to whether balance billing and in-network cost sharing protections apply to the item or service, and provide to the plan or issuer a signed copy of any signed written notice and consent documents. With respect to non-emergency services described in 45 CFR 149.410(a), the nonparticipating provider (or the participating facility on behalf of the provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility. With respect to post-stabilization services, the nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer as to whether all the conditions described in 45 CFR 149.410(b) are met with respect to each of the items and services for which the bill is submitted. With respect to non-emergency services only, in instances where the nonparticipating provider bills the participant, beneficiary, or enrollee directly (where permitted under these interim final rules), the provider (or participating health care facility on behalf of the provider) may satisfy the requirement to timely notify the plan or issuer by including the notification with the bill to the individual.

In interpreting the statutory requirements, HHS recognizes that it is critical that a group health plan or health insurance issuer have knowledge of whether the balance billing and in-network cost-sharing requirements apply, including whether an item or service is furnished during a visit at a participating health care facility and if any notice was provided and consent given what items and services were consented to, where such items and

services would otherwise be subject to the balance billing protections. This information is crucial for the plan or issuer to be able to appropriately assign cost sharing and adjudicate the claim in compliance with the No Surprises Act. These interim final rules require the provider or facility to notify the plan or issuer so that the plan or issuer is aware when the balance billing and in-network cost sharing protections apply and can process the claim appropriately.⁹¹

HHS seeks comment on whether additional rulemaking would be helpful regarding the process and timing for such notification, including the definition of ‘timely,’ and what processes for conveying the notification would be most efficient, including existing processes that could be leveraged to convey the information. HHS is particularly interested in comments regarding the requirement that providers or facilities provide to the plan or issuer a copy of the signed written notice and consent document, including comments on barriers and burdens associated with such requirement, and recommendations on how best to ensure plans and issuers have information regarding the notice and consent documents without imposing undue burden on providers and facilities.

3. Provider and Facility Disclosure Requirements Regarding Patient Protections Against Balance Billing

Section 2799B–3 of the PHS Act, added by the No Surprises Act, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Among other things, the statute requires health care providers and facilities (including an emergency department of a hospital or independent freestanding emergency department) to make publicly available, post on a public website of the provider or facility (if applicable), and provide to participants, beneficiaries, and enrollees a one-page notice about the balance billing requirements and prohibitions that apply to the provider or facility under sections 2799B–1 and 2799B–2 of the

PHS Act. The notice must include information about any applicable state requirements, and about how to contact appropriate state and federal agencies if the individual believes the provider or facility has violated the balance billing rules. These interim final rules codify the statutory requirements and information that these disclosures must include. In addition, as stated previously, under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act, plans and issuers must provide information in plain language on the prohibition against balance billing and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing. These disclosure requirements are applicable for plan years beginning on or after January 1, 2022. To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a model disclosure notice that health care providers, facilities, group health plans, and health insurance issuers may, but are not required to, use to satisfy the disclosure requirements regarding the balance billing protections. The Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act, if all other applicable requirements are met. The Departments may address these requirements in more detail in future guidance or rulemaking. Until such guidance or rulemaking implementing the requirements under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act becomes effective and applicable, plans and issuers should exercise good-faith compliance with those statutory provisions.

These disclosures are critical to helping raise awareness and enhance the public’s understanding of state and federal balance billing protections. The purpose of these disclosures is to empower individuals to better understand the balance billing protections afforded under applicable state and federal law. In addition, these disclosures are important in ensuring individuals are able to identify violations of these interim final rules and related state law requirements and, if necessary, file complaints against providers and facilities. These disclosures further the efforts to help

achieve the goals of the No Surprises Act and ensure that individuals are aware of their rights and the options available to them. These interim final rules codify the provider and facility disclosure requirements at 45 CFR 149.430. These requirements apply to health care providers and health care facilities (including independent freestanding emergency departments). These interim final rules outline requirements regarding the content of the one-page disclosure, methods for disclosure, timing of disclosure to individuals, exceptions to the requirements, and a special rule to prevent unnecessary duplication with respect to providers. These disclosure requirements do not apply to providers of air ambulance services, as section 2799B–3 of the PHS Act requires providers and facilities to disclose information regarding the requirements and prohibitions applicable to the provider or facility under sections 2799B–1 of the PHS Act (relating to balance billing for emergency services) and 2799B–2 of the PHS Act (relating to balance billing for non-emergency services furnished by nonparticipating providers at certain participating facilities), but not under section 2799B–5 of the PHS Act (relating to balance billing for air ambulance services). Although this provision does not apply to providers of air ambulance services, as the definition of health care providers in 45 CFR 149.30 excludes providers of air ambulance services, HHS encourages providers of air ambulance services to make available clear and understandable information about the requirements and prohibitions on balance billing for air ambulance services.

i. Content of Disclosure

The statute and these interim final rules require that the disclosure must include a clear and understandable statement that explains the requirements and prohibitions applicable to the provider or facility under sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations, relating to prohibitions on balance billing in cases of emergency services and non-emergency services performed by a nonparticipating provider at certain participating facilities as described earlier in this preamble.

In addition, the disclosure must include clear and understandable language that explains any applicable state law requirements regarding the amounts such provider or facility may charge a participant, beneficiary, or enrollee after receiving payment, if any,

⁹¹ The Departments note that whether a provider or facility provides such a notification to the plan or issuer and whether a plan or issuer processes a claim as if notice and consent were obtained based on a provider’s notification is not determinative of whether the balance billing protections apply. A participant, beneficiary, or enrollee who is balance billed or whose cost-sharing responsibility is calculated at out-of-network rates would still be able to contend that they did not receive sufficient notice or did not provide consent, and challenge the provider or facility’s right to balance bill them, as well as and the plan or issuer’s handling of the claim.

from a plan or coverage (with which the provider or facility does not have a contractual relationship) and any applicable cost-sharing payment from such participant, beneficiary, or enrollee.

HHS recognizes that there may be some state laws that are more protective of consumers than sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations. For example, a state law might prohibit an individual from providing consent to be balance billed under more circumstances than those in which balance billing are prohibited under those sections and their implementing regulations. If the more protective state law causes certain provisions of sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations to be inapplicable to the provider or facility, the provider or facility is not required to include language containing information on those inapplicable provisions in the disclosures regarding the federal requirements and prohibitions, to the extent permitted under state law. However, the provider or facility would continue to be required to include information in the disclosures about any provisions in sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations that remain applicable to the provider or facility.

Last, the statute and these interim final rules require that the disclosure must include clear and understandable language providing contact information for the appropriate state and federal agencies that an individual may contact if the individual believes the provider or facility has violated a requirement described in the notice. If only one federal or state agency has oversight with respect to providers or facilities in the state, the disclosure may include contact information for only that agency.

In an effort to reduce the burden on health care providers and facilities, HHS has developed a model notice that health care providers and facilities may adopt, but are not required to use. HHS would consider a provider or facility that uses the HHS-developed model notice to be compliant with these federal disclosure rules with respect to the information regarding sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations. HHS encourages states to develop model language to assist health care providers and facilities in fulfilling the disclosure requirements related to applicable state law requirements and contact information. If a state develops model language that is consistent with section

2799B–3 of the PHS Act, HHS will consider a provider or facility that makes appropriate use of the state-developed model language to be compliant with the federal requirement to include information about state law protections.

To ensure clear and understandable language for the required information, HHS encourages health care providers and facilities to utilize plain language in the disclosure statements and to consider user testing in the development of such notices.⁹² Providers and facilities must comply with applicable state or federal language access standards in providing the disclosures.⁹³ Communication and language barriers are associated with decreased quality of care and poorer health outcomes.⁹⁴ Studies have shown the benefits associated with the use of language services in clinics and hospitals include (1) increased quality of care, (2) improved patient safety outcomes, and (3) lower utilization of costly medical procedures. The presence of a language barrier is associated with higher rates of costly resource utilizations for diagnostic testing, increased emergency department visits, decreased use of preventive services, higher rates of hospitalization, and higher rates of adverse health outcomes.⁹⁵ HHS believes it is imperative that health care providers and facilities provide the required disclosure information in a clear and understandable manner to help achieve the goal of the No Surprises Act and ensure that individuals are aware of their rights related to protections against balance billing.

In addition, HHS reminds health care providers and facilities that these notices must comply with applicable federal civil rights laws, including that

providers and facilities must take reasonable steps to provide meaningful access for individuals with limited English proficiency and appropriate steps to ensure effective communication with individuals with disabilities, including accessibility of information and communication technology.

HHS seeks comment on the content of the required disclosures. Consistent with Executive Order 13985 and civil rights protections cited in these interim final rules, HHS particularly seeks comments from minority and underserved communities, including from those with limited English proficiency, those who prefer information in alternate and accessible formats, those who are otherwise adversely affected by persistent poverty and inequality, as well as from stakeholders who serve these communities, on what additional barriers may exist so as to ensure individuals can read, understand, and consider disclosure information and on what policies HHS may consider for addressing and removing these barriers.

ii. Methods of Disclosure

The statute and these interim final rules require that each health care provider and facility must make the required disclosure publicly available, and (if applicable) post it on a public website of such provider or facility. In addition, providers and facilities must provide a one-page notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or individual health insurance coverage offered by a health insurance issuer.

To satisfy the requirement to post the disclosure on a public website, the disclosure or a link to such disclosure must be searchable on the provider's or facility's public website. HHS is of the view that the required disclosure information would not be publicly available unless displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including that it is findable through public search engines. For example, HHS is of the view that a public website must be accessible free of charge, without having to establish a user account, password, or other credentials, accept any terms or conditions, and without having to submit any personal identifying information such as a name or email address. HHS seeks comment on whether additional regulatory standards are needed regarding what constitutes disclosure on a provider's or facility's public website to ensure the information is accessible to the public.

⁹² See <https://methods.18f.gov/> for information on user testing.

⁹³ See section IV.2.iii of this preamble for discussion of select federal access standards.

⁹⁴ <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan-508.pdf>.

⁹⁵ See Dewalt DA, Berkman ND, Sheridan S, Lohr KN, Pignone MP. Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med.* 2004;19(12):1228–1239. doi:10.1111/j.1525-1497.2004.40153.x; Scott TL, Gazmararian JA, Williams MV, Baker DW. Health literacy and preventive health care use among Medicare enrollees in a managed care organization. *Med Care.* 2002;40:395–404; Baker DW, Parker RM, Williams MV, Clark WS. Health literacy and the risk of hospital admission. *J Gen Intern Med.* 1998;13:791–8; Neira L. The importance of addressing language barriers in the US health system. Duke Center for Personalized Health Care (July 17, 2018), available at: <https://dukepersonalizedhealth.org/2018/07/the-importance-of-addressing-language-barriers-in-the-us-health-system/>.

These interim final rules provide that a health care provider or health care facility that does not have its own website is not required to make a disclosure on a public website. HHS anticipates that most facilities subject to the requirements in sections 2799B–1 and 2799B–2 of the PHS Act would generally have a website, but recognizes that providers who furnish services at such facilities may not have their own website.

To satisfy the required disclosure to the public, providers and facilities must display the required disclosure information on a sign posted prominently at the location of the health care provider or health care facility. HHS would consider a sign to be posted prominently, if the sign were posted in a central location, such as where individuals schedule care, check-in for appointments, or pay bills. Such locations would allow individuals to be aware of the protections available before or at the time of service or payment. HHS is of the view that ensuring the individual is aware of the surprise billing protections is integral to implementation of these requirements. HHS recognizes that some providers may not have publicly accessible locations and has concluded that requiring a sign to be posted prominently at a non-publicly accessible location would not further the purpose of providing a disclosure. Therefore, providers without a publicly accessible location are not required to make the disclosure under 45 CFR 149.430(c)(2).

Lastly, the statute and these interim final rules require that health care providers and facilities must provide the required disclosure information in a one-page notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer. The notice must be provided in-person or through mail or email, as selected by the participant, beneficiary, or enrollee. As outlined in the statute, the required disclosure to individuals must be limited to one page. HHS interprets the statute such that the disclosure notice may be one double-sided page. These interim final rules specify that the one-page disclosure must not include print smaller than 12-point font. These specifications are important to ensure that the one-page document is both designed in a form and presented in a manner that is readable by the individual or their representative and that it contains sufficient content to meet the requirements of these interim final rules.

HHS seeks comment on these disclosure methods, including whether additional methods of providing information should be required or permitted. In particular, HHS is interested in comments regarding whether posting of the disclosure information could be in a location other than a sign posted prominently at the location of the provider or facility. In addition, HHS seeks comment on ways to ensure that the required disclosure information posted on a public website is accessible to individuals.

iii. Timing of Disclosure to Individuals

These interim final rules generally require a health care provider or health care facility to provide the notice to participants, beneficiaries, or enrollees no later than the date and time on which the provider or facility requests payment from the individual (including requests for copayment made at the time of a visit to the provider or facility). In cases where the facility or provider does not request payment from the individual, the notice must be provided no later than the date on which the provider or facility submits a claim for payment to the plan or issuer.

HHS is of the view that the notice will be most effective in helping individuals understand their rights and protections under federal and state balance billing laws and protecting individuals from being improperly billed, if individuals receive the notice in accordance with this timing requirement. The requirement will ensure the disclosures are meaningful and that individuals are aware of their rights before or at the time of payment, which is likely to help individuals to avoid paying bills that are prohibited under state or federal balance billing rules. However, these interim final rules offer providers and facilities flexibility regarding when the disclosure must be provided to individuals. Providers and facilities may provide the required disclosures to individuals earlier. For example, they could provide the notice when an individual schedules an appointment, or when other standard notice disclosures (such as the Notice of Privacy Practices for Protected Health Information⁹⁶) are shared with individuals.

In developing these interim final rules, HHS considered allowing providers or facilities to provide the disclosure annually or only at the time a patient schedules a service, but wanted to ensure the timing of the disclosure was relevant to when the

individual may experience a violation of the surprise billing protections. HHS encourages providers and facilities to provide individuals with the notice at a time that will maximize the notice's effectiveness.

HHS seeks comment on this timing requirement, and whether another timing requirement would be more appropriate.

iv. Exceptions

Although section 2799B–3 of the PHS Act could be interpreted to apply broadly to all health care providers and facilities, these interim final rules include two exceptions to the general requirement to provide disclosures regarding balance billing protections. First, health care providers are not required to make the disclosures required under this section if they do not furnish items or services at a health care facility, or in connection with visits at health care facilities. Second, health care providers are required to provide the required disclosure only to individuals to whom they furnish items or services, and then only if such items or services are furnished at a health care facility, or in connection with a visit at a health care facility. HHS further notes that, under section 2799B–3 of the PHS Act, disclosure is required only to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer. However, as specified in 5 U.S.C. 8902(p), section 2799B–3 of the PHS Act applies to a health care provider and facility with respect to a covered individual in a FEHB plan, as well. The disclosure requirement is not required with respect to other individuals seeking care from a provider or facility.

While the statute does not explicitly provide for these exceptions, HHS is of the view that these exceptions serve two important purposes. First, they seek to avoid unnecessary confusion among individuals who otherwise might receive the disclosure under circumstances in which the balance billing protections would never apply. For instance, providing the disclosure of balance billing protections in a primary care provider's office could lead individuals to incorrectly assume balance billing protections exist where they do not. Second, by ensuring that the disclosures are targeted narrowly to relevant individuals, the exceptions aim to implement the statutory requirement without creating additional undue burden on providers and facilities.

HHS is of the view that these exceptions are consistent with balance

⁹⁶For requirements regarding when health care providers are required to provide the Notice of Privacy Practices, see 45 CFR 164.520(c).

billing requirements elsewhere in these interim final rules, related to emergency services or non-emergency services furnished by a nonparticipating provider at a participating facility. Furthermore, HHS is of the view that these exceptions do not lessen the positive impact of the disclosure requirement, as health care providers and facilities are still required to make the disclosures where balance billing is most likely to occur, which will help to ensure individuals are aware of their rights relating to consumer protections against balance billing.

HHS seeks comment on these exceptions and whether there are other scenarios that should be considered.

v. Special Rule To Prevent Unnecessary Duplication With Respect to Providers

HHS realizes there may be some instances where an individual may receive two disclosure notices—one from a provider furnishing items or services at a health care facility, and the other from the health care facility itself. These interim final rules include a special rule to streamline the provision of the required disclosure to the public and one-page notice to individuals and avoid unnecessary duplication of the disclosures with respect to providers furnishing care at a health care facility. This special rule does not apply with respect to the requirement that each health care provider and facility post the required disclosure on a public website of such provider or facility. While section 2799B–3 of the PHS Act does not explicitly provide for a special rule to prevent unnecessary duplication with respect to providers, HHS is of the view that this special rule serves an important purpose in implementing these requirements while reducing unnecessary burden and effort for providers. Furthermore, HHS is of the view that this special rule will also help reduce potential consumer confusion by allowing individuals to receive only one disclosure notice when receiving services from a provider furnishing items or services at a health care facility, both of which are subject to the disclosure requirement.

The special rule provides that to the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency department of a hospital or independent freestanding emergency department), the provider satisfies the disclosure requirements if the facility agrees to provide the information, in the required form and manner, pursuant to a written agreement. In such instance, the disclosure must include information

about the balance billing requirements and prohibitions applicable to both the facility and the provider. If a provider and facility have a written agreement under which the facility agrees to provide the information required under these interim final rules, and the facility fails to provide full or timely disclosure information, then the facility, but not the provider, would violate the provider disclosure requirements regarding balance billing protections. HHS is of the view that this will remove unnecessary burden and effort for the providers. HHS clarifies that a “written agreement” may be an existing contract between the provider and facility to furnish care at the facility, if amended to provide for this special rule. Alternatively, a provider and facility may enter into a new written agreement specifically outlining the disclosure requirements regarding balance billing protections.

Providers that enter into these arrangements with facilities are encouraged to monitor the facility’s adherence to these requirements. In addition, if a provider has knowledge that the required disclosure information is not being provided in a manner specified in these interim final rules, HHS encourages the provider to work with the facility to correct the noncompliance as soon as practicable or notify the applicable state authority or HHS, in states where HHS is enforcing this requirement.⁹⁷ HHS may provide additional guidance if HHS becomes aware of situations where participants, beneficiaries, and enrollees are not being provided the required disclosure information in accordance with these interim final rules.

HHS recognizes that providers and facilities frequently bill separately for items and services furnished by the provider and the facility, and considered whether to make the special rule inapplicable in those instances. However, HHS concluded that applying the special rule is appropriate in these situations, since the disclosures are not required to be included with the bill itself. Although these interim final rules provide some flexibility around the timing of the notice, HHS anticipates that the disclosure to the individual would generally be provided at the point of care. Thus, requiring the

provider and facility to separately provide notices whenever they bill separately could result in the individual receiving multiple notices for the same visit. Duplicative paperwork could overwhelm or confuse the receiving individual, which could detract from the primary purpose of clarifying and making known the protections that may apply to the individual. In addition, HHS is of the view that requiring a provider to separately post a disclosure within a facility is of limited additional benefit and may present compliance challenges for providers who lack designated space within a facility. Therefore, the special rule applies regardless of whether the provider and facility bill jointly or separately.

Furthermore, since the special rule does not apply with respect to the requirement that each health care provider and facility make the required disclosure available on the public website of the provider or facility, HHS is of the view that this special rule works to achieve the goals of preventing unnecessary duplication for providers and facilities, while encouraging safeguards to ensure that individuals receive the required disclosure information and are aware of their rights. HHS is of the view that this special rule does not lessen the positive impact of the disclosure requirement. This special rule will continue to help to ensure individuals are aware of their rights relating to patient protections against surprise billing.

HHS seeks comment on this special rule and whether there are other circumstances that may warrant a special rule to prevent unnecessary duplication. In addition, HHS seeks comment on whether providers should be required, rather than encouraged, to monitor and report whether a facility is not complying with the requirement outlined in these interim final rules.

4. Surprise Billing Complaints Regarding Health Care Providers, Facilities, and Providers of Air Ambulance Services

The No Surprises Act adds section 2799B–4(b)(3) of the PHS Act, which directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services of balance billing requirements under sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act and to respond to such complaints within 60 days. Therefore, the interim final rules establish an HHS-only complaints process for health care providers, facilities and providers of air ambulance services that parallels the

⁹⁷ Pursuant to section 2799B–4 of the PHS Act, states have authority to enforce the requirements of Part E of title XXVII of the PHS Act against a provider or health care facility (including a provider of air ambulance services), and HHS must enforce if a state has failed to substantially enforce the requirements. HHS intends to issue rulemaking in the future to implement section 2799B–4 of the PHS Act.

process that the Departments are establishing through these interim final rules for plans and issuers. A more fulsome discussion of the complaints process for providers can be found in section III.B.4 of this preamble. HHS seeks comment on the complaints process for health care providers, facilities, and providers of air ambulance services described in these interim final rules.

5. Catastrophic Plans

As discussed earlier in this preamble, where the surprise billing protections apply, and the out-of-network rate exceeds the amount upon which cost sharing is based (which for emergency services provided by a nonparticipating emergency facility and for non-emergency services provided by a nonparticipating provider at a participating health care facility is the recognized amount, and for services provided by a nonparticipating provider of air ambulance services is the lesser of the billed amount or the QPA), a group health plan or health insurance issuer offering group or individual health insurance coverage must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount, even in cases where an individual has not satisfied their deductible (in which case the cost-sharing amount is the recognized amount, or the lesser of the billed amount or the QPA, as applicable). Catastrophic plans generally cannot provide benefits for any plan year until the annual limitation on cost sharing in section 1302(c)(1) of ACA is reached, other than coverage of preventive services under section 2713 of the PHS Act and at least three primary care visits. A catastrophic plan cannot comply with the new balance billing protections, specifically the obligation to make a payment to a provider or facility prior to the enrollee meeting the annual limitation on cost sharing, while satisfying the definition of a catastrophic plan at section 1302(e) of ACA. Because the No Surprises Act does not contain language eliminating catastrophic plans or exempting catastrophic plans from the law's requirements, HHS interprets the statute as permitting catastrophic plans to make payments required by sections 2799A–1 or 2799A–2 of the PHS Act without losing their status as catastrophic plans. HHS is, therefore, amending 45 CFR 156.155 in these interim final rules to specify that a catastrophic plan must provide benefits as required under sections 2799A–1 and 2799A–2 of the PHS Act and their implementing regulations, or any applicable state law

providing similar surprise billing protections to individuals. Additionally, a health plan will not fail to be treated as a catastrophic plan because the plan provides benefits prior to the annual limitation on cost sharing in section 1302(c)(1) of the ACA, as required under sections 2799A–1 and 2799A–2 of the PHS Act or any applicable state law providing similar protections to individuals.

V. Overview of Interim Final Rules—Office of Personnel Management

A. Conforming Changes for FEHB Program

The OPM interim final rules, through new 5 CFR 890.114 in subpart A, protect FEHB Program covered individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating health care facilities in certain circumstances in the same manner as the Departments' rules protect participants, beneficiaries, or enrollees. The Departments' interim final rules generally apply with respect to FEHB carriers' compliance with the No Surprises Act, except to the extent that differences are necessitated for clarification or appropriate application in the context of the FEHB Program. In considering application of the Departments' interim rules with respect to the FEHB Program, it is important to recognize that all FEHB carriers offer fully insured health benefits plans in consideration of premium payments pursuant to contract terms, and no health benefits plan is self-insured by OPM or the Federal government. OPM seeks comment on this approach and whether there should be any additional considerations in the application of these interim final rules in the context of the FEHB Program.

B. Preemption and OPM Enforcement

FEHB contract terms preempt state law with respect to coverage or benefits (including payments with respect to benefits) pursuant to 5 U.S.C. 8902(m)(1). Such preemption renders specified state law inapplicable for the purposes of determining recognized amounts and out-of-network rates under 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 149. However, pursuant to bilateral negotiation of FEHB contract terms, OPM and the carrier may agree to apply state law to determine the total amount payable, rendering the state law amount, method, or process for determining the total amount payable an effective term of the Federally-regulated,

Federally-enforced contract. Accordingly, in this instance, FEHB contract terms will govern the methodology for determining recognized amounts and out-of-network rates. In the absence of a FEHB contract term incorporating a state law amount, method, or process for determining the total amount payable (including an amount determined pursuant to an All-Payer Model Agreement under section 1115A of the Social Security Act), the lesser of the billed amount or the QPA will serve as the recognized amount under the FEHB plan. Likewise, in the absence of a FEHB contract term incorporating an applicable state IDR process, the federal IDR process will govern the determination of out-of-network rates in cases of failed open negotiations.

Example A: A community-rated FEHB plan covers a specific non-emergency service that is provided to a covered individual in State A by a nonparticipating provider in a participating health care facility. Both the provider and the facility are licensed in State A. State A has a law that prohibits balance billing for non-emergency services provided to individuals by nonparticipating providers in a participating health care facility, and provides for a method for determining the cost-sharing amount and total amount payable. The law applies to health insurance issuers and providers licensed in State A and applies to the type of service provided. OPM and the FEHB carrier, through the annual contract negotiation cycle, have elected to utilize State A's law, and the FEHB health benefits plan contains a term expressly incorporating the State A law prohibiting balance billing. In this Example, the FEHB contract terms apply the state law to determine the recognized amount and the out-of-network rate.

Example B: Same facts as Example A, except that the FEHB contract terms do not incorporate or expressly refer to the balance billing law of State A. In this Example, State A's law prohibiting balance billing would be preempted by the terms of the FEHB contract. The lesser of the billed amount or QPA would apply to determine the recognized amount. The out-of-network rate would be determined through open negotiation between the nonparticipating provider and the FEHB carrier, or in the case of failed negotiations, an amount determined under the federal IDR process.

Enforcement of these interim final rules with respect to FEHB carriers will generally be governed by OPM authorities set forth herein and 5 U.S.C.

8901 *et seq.*, 5 CFR part 890, 48 CFR chapter 16, or the carrier's FEHB contract. Any differences in terminology or other clarification will be set forth in the applicable FEHB contract.

C. Definitions

The No Surprises Act and these interim final rules include defined terms that are specific to the law's requirements and implementation. Definitions of key terms with respect to OPM's enforcement of 5 U.S.C. 8902(p) generally align with the Departments' regulations, with certain exceptions. For compliance with these provisions, the terms "group health plan or plan," "health insurance issuer or issuer," and "participant, beneficiary, or enrollee" are respectively replaced with the terms "health benefits plan," "carrier," and "enrollee or covered individual."

D. Complaints

Complaints related to the provisions under Part D of title XXVII of the PHS Act with respect to carriers and FEHB plans will generally be resolved in accordance with the Departments' interim final rules. OPM will coordinate with the Departments to ensure that complaints appropriate for OPM resolution under the FEHB Program statute, regulations or contractual authorities are referred to OPM.

E. Jurisdiction of Courts

Under 5 U.S.C. 8912, the district courts of the United States have original jurisdiction, concurrent with the United States Court of Federal Claims, of a civil action or claim against the United States founded on FEHBA. Pursuant to new paragraph (e) in 5 CFR 890.107, in the event of litigation under these interim final rules, a suit for equitable relief founded on 5 U.S.C. chapter 89 that is based on 5 U.S.C. 8902(p) and is governed by 5 CFR part 890 must be brought against OPM by December 31 of the 3rd year after the year in which disputed services were rendered. OPM seeks comment on amendments to its regulation on court review.

F. Applicability

OPM seeks comment on the appropriate manner of conforming compliance with sections 9816, 9817, and 9822 of the Code; sections 716, 717, and 722 of ERISA; and sections 2799A–1, 2799A–2, and 2799A–7 of the PHS Act for application to FEHB carriers, including the appropriateness and usability of the definitions and any additional changes to the Departments' regulatory provisions that must be conformed for appropriate implementation in the FEHB Program.

For purposes of 5 U.S.C. 8902(p), the HHS interim final rules apply to health care providers, facilities, and providers of air ambulance services with respect to covered individuals in a FEHB plan in the same manner as they apply with respect to participants, beneficiaries, and enrollees in a group health plan or group or individual health insurance coverage offered by a health insurance issuer. OPM seeks comment on the appropriate manner of conforming compliance with 5 U.S.C. 8902(p) and sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act.

Consistent with the Departments' approach discussed in section III.D. of this preamble, OPM will not apply these interim final rules to health benefits plans that are retiree-only plans.

VI. Waiver of Proposed Rulemaking

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries), respectively, to promulgate any interim final rules that they determine are necessary or appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act.

In addition, under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. The Secretaries and OPM Director have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until after a full public notice and comment process has been completed.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act, 2021. The cost-sharing and balance billing requirements on plans, issuers, health care providers, facilities, and providers of air ambulance services in the No Surprises Act apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022. Although this effective date may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions in the No Surprises Act, this timeframe would not provide sufficient time for the regulated entities to implement the requirements. These interim final rules require plans

and issuers to make significant changes to how they pay for items and services that are subject to the cost-sharing and balance billing protections, including implementing claims processing procedures to ensure that claims for items and services subject to these protections are processed in accordance with the requirements in these interim final rules. Group health plans and health insurance issuers offering group or individual health insurance coverage will have to account for these changes in establishing their premium or contribution rates, and in making other changes to the designs of plan or policy benefits. In some cases, issuers will need time to secure approval for these changes in advance of the plan or policy year in question. The Departments and OPM anticipate the plans and issuers will have already taken into consideration the statutory provisions in the No Surprises Act as they developed plan designs for 2022, and preliminary rates. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking, may allow plans and issuers to account for the finalized regulations as they finalize rates and plan offerings.

The interim final rules place new requirements on facilities, health care providers, and providers of air ambulance services regarding when they are permitted to balance bill for items and services. Such requirements include new requirements related to how providers and facilities must bill for items and services furnished on an out-of-network basis, requirements related to providing notice and obtaining consent regarding balance billing protections in certain circumstances, and requirements to disclose information on balance billing publicly, on a public website and to participants, beneficiaries, and enrollees. Health care providers and facilities require time to implement these new requirements to ensure compliance by January 1, 2022.

These interim final rules contain critical protections for participants, beneficiaries, and enrollees against balance billing. For individuals who receive balance bills, the costs can be astronomical and devastating.⁹⁸ In addition, the recipients of such bills are not the only ones who feel their impact. As discussed elsewhere in this preamble, providers have previously been able to leverage the ability to

⁹⁸ See, Greaney, T.L., Surprise Billing: A Window into the U.S. Health Care System, ABA Civil Rights and Social Justice Section, Human Rights Magazine (Sept. 8, 2020); Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 20173623 (July 2017, Revised January 2018).

balance bill to negotiate higher in-network rates. This leads to higher premiums, higher cost sharing for consumers, and increased health expenditures.⁹⁹ One study estimated that policies to address surprise billing on a federal level could decrease health insurance premiums by one to five percent.¹⁰⁰ Additionally, consumers may delay receiving needed medical care, including for emergency medical conditions, over concern about surprise medical bills. It is therefore in the public interest that individuals receive the protections under the No Surprises Act on the date on which those protections go into effect. Accordingly, in order to allow plans, health insurance issuers, facilities, health care providers, and providers of air ambulance services sufficient time to implement these new requirements, these rules must be published and available to the public well in advance of the effective date of the requirements in the No Surprises Act. Allowing time for a full notice and comment process prior to the requirements taking effect would not provide sufficient time for these entities to comply with the requirements for plan years (in the individual market, policy years) beginning on or after January 1, 2022, which would risk subjecting the public to prohibited balance bills and excess cost sharing. Additionally, plans and issuers need certainty regarding the standards of these requirements in order to begin implementation, which these interim final rules seek to provide.

Section 2723 of the PHS Act authorizes states to enforce the requirements in Part D of title XXVII of the PHS Act with respect to issuers. Section 2799B–4 of the PHS Act authorizes states to enforce the requirements in Part E of title XXVII of the PHS Act with respect to providers and health care facilities (including a provider of air ambulance services). Under both sections, HHS is required to enforce such requirements if a state fails to substantially enforce them. In order to ensure effective oversight of these new requirements as soon as they go

into effect, states require time to assess the requirements contained in these interim final regulations, and notify HHS if they have not enacted legislation to enforce such requirements or they otherwise will not be enforcing such requirements. States that opt to enforce the requirements may require time to update their regulations or statutes and develop processes for enforcing the new requirements. Delaying the rules to allow for notice and comment procedures would not provide sufficient time for states to assess the new requirements and notify HHS of their ability to enforce.

In addition, the law requires the Secretaries to issue rulemaking by July 1, 2021, regarding the QPA methodology (including defining the geographic regions for purposes of the methodology); information plans or issuers must share with nonparticipating providers or facilities, as applicable, regarding the plan or issuer's determination of the QPA; and a process to receive complaints related to the QPA. Allowing time for a full notice and comment process prior to July 1, 2021, would not have provided sufficient time for the Departments to develop and publish these rules by the statutory deadline.

For the foregoing reasons, the Departments and OPM have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules.

VII. Economic Impact and Paperwork Burden

A. Summary

These interim final rules implement provisions of the No Surprises Act, which Congress enacted as part of the CAA, that protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at certain participating facilities, and air ambulance services, under certain circumstances.

The Departments and OPM¹⁰¹ have examined the effects of these interim final rules as required by Executive Order 13563 (76 FR 3821, January 21, 2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993,

Regulatory Planning and Review); the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354); section 1102(b) of the Social Security Act (42 U.S.C. 1102(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4); Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism); and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

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 one 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 must be prepared for major rules with economically significant effects (for example, \$100 million or more in any one year), and a “significant” regulatory action is subject to review by OMB. The Departments anticipate that this regulatory action is likely to have economic impacts of \$100 million or more in at least 1 year, and thus meets the definition of an “economically significant rule” under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with these interim final rules. In accordance with the provisions of Executive Order 12866, these interim final rules were reviewed by OMB.

⁹⁹ See Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 20173623 (July 2017, Revised January 2018); Duffy, E. et al., “Policies to Address Surprise Billing Can Affect Health Insurance Premiums.” The American Journal of Managed Care 26.9 (2020): 401–404; and Brown E.C.F., et al., The Unfinished Business of Air Ambulance Bills, Health Affairs Blog, March 26, 2021. DOI: 10.1377/hblog20210323.911379, available at <https://www.healthaffairs.org/doi/10.1377/hblog20210323.911379/full/>.

¹⁰⁰ Trish E. et al., Policies to Address Surprise Billing Can Affect Health Insurance Premiums, Am J Manag Care. 2020;26(9):401–404. <https://doi.org/10.37765/ajmc.2020.88491>.

¹⁰¹ All references to the Departments in the Economic Impact section of the preamble include OPM. The analysis includes FEHB plans.

1. Need for Regulatory Action

A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a participant, beneficiary, or enrollee receives medical services from a provider (including a provider of air ambulance services) or facility that, generally unbeknownst to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. Surprise bills usually occur in situations when a patient is unable to choose a provider (including a provider of air ambulance services) or emergency facility and ensure that they receive care from only providers or emergency facilities that are participating for their coverage. A recent survey revealed that two-thirds of adults worry about being able to afford unexpected medical bills for themselves and their families, and 41 percent of adults with health insurance received a surprise medical bill in the previous 2 years.¹⁰² Surprise bills can cause significant financial hardship and cause individuals to forgo care. A project carried out by Vox, a news and opinion website, which collected emergency department medical bills reported instances of accident victims receiving care at out-of-network hospitals and receiving bills of over \$20,000.¹⁰³ These challenges may be more keenly experienced by minority and underserved communities, which are more likely to experience poor communication, underlying mistrust of the medical system, and lower levels of patient engagement than other

populations.¹⁰⁴ Communities experiencing poverty and other social risk factors are particularly impacted as surprise medical bills can negatively affect individuals' abilities to eliminate debt and create wealth, and ultimately can affect a family for generations.¹⁰⁵ Effective, culturally, and linguistically tailored communication at appropriate literacy levels, along with policies that address the social risk factors and other barriers underserved communities face to accessing, trusting, and understanding health care costs and coverage can reduce disparities and promote health equity.¹⁰⁶

¹⁰⁴ Butler S., Sherriff N. How poor communication exacerbates health inequities and what to do about it. Brookings Institution: Report (February 22, 2021). <https://www.brookings.edu/research/how-poor-communication-exacerbates-health-inequities-and-what-to-do-about-it/>; Hamel, L., Lopes, L., Muñana, C., Artiga, S., Brodie, M. Race, Health, and COVID-19: The Views and Experiences of Black Americans. Kaiser Family Foundation (October 2020). <https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>; and Shen M.J., Peterson E.B., Costas-Muñiz R. *et al.* The Effects of Race and Racial Concordance on Patient-Physician Communication: A Systematic Review of the Literature. *J. Racial and Ethnic Health Disparities* 5, 117–140 (2018). <https://doi.org/10.1007/s40615-017-0350-4>.

¹⁰⁵ Taylor, J., Racism, inequality, and health care for African Americans. The Century Foundation: Report (December 19, 2019). <https://tcf.org/content/report/racism-inequality-health-care-african-americans/>; and Chavis, B., Op-Ed: Big insurance must help end surprise medical billing. *blackpressUSA* (February 24, 2020). <https://blackpressusa.com/op-ed-big-insurance-must-help-end-surprise-medical-billing/>.

¹⁰⁶ Pérez-Stable E.J., El-Toukhy S., Communicating with diverse patients: How patient and clinician factors affect disparities. *Patient Educ Couns.* 2018;101(12):2186–2194. doi:10.1016/j.pec.2018.08.021; McNally, M., Confronting disparities in access to healthcare for underserved populations. *MedCity News* (February 22, 2021). <https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/>.

¹⁰² Pollitz K., *et al.*, US Statistics on Surprise Medical Billing. *JAMA.* 2020;323(6):498. doi:10.1001/jama.2020.0065.

¹⁰³ Kliff S., Surprise medical bills, the high cost of emergency department care, and the effects on patients [published online August 12, 2019]. *JAMA Intern Med.* doi:10.1001/jamainternmed.2019.3448.

The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise medical bills arise most frequently. These interim final rules implement provisions of the No Surprises Act that protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.

2. Summary of Impacts

The provisions in these interim final rules will ensure that participants, beneficiaries, and enrollees with health coverage are protected from surprise medical bills. Individuals with health coverage will gain peace of mind, experience a reduction in out-of-pocket expenses, be able to meet their deductible and out-of-pocket maximum limits sooner, and may experience increased access to care. Plans, issuers, health care providers, facilities, and providers of air ambulance services will incur costs to comply with the requirements in these interim final rules. In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. The Departments are unable to quantify all benefits, costs, and transfers of these interim final rules but have sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these interim final rules.

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TABLE 1: Accounting Statement

Benefits:				
Non-Quantified:				
• Elimination of surprise medical bills for individuals from out-of-network medical care and air ambulance services. • Reduction in financial anxiety, including anxiety associated with medical debt, for individuals with health coverage, due to a reduction in surprise bills. • Increased access to care for individuals with health coverage that may have otherwise forgone or neglected needed treatment due to high out-of-pocket expenses, and better health outcomes as a result. Potential improved health outcomes for individuals with grandfathered health coverage due to the ability to choose their own primary care physicians, the ability to choose a pediatrician as the primary care physician for children, and the ability to receive obstetrical and gynecological care without a referral.				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$ 2,252.23 million	2021	7 percent	2021 – 2025
	\$ 2,177.12 million	2021	3 percent	2021 – 2025
Quantitative:				
• Costs to issuers and third-party administrators (TPAs) to comply with the requirements related to the recognized amount and QPA, estimated to be one-time costs of approximately \$4,958 million to make the necessary information technology system changes in 2021 and ongoing operational costs of \$2,047 million in 2022 and \$724 million annually from 2023 onwards. • Costs to issuers and TPAs to revise standard operating procedures and provide training to staff, estimated to be one-time costs of approximately \$12.1 million in 2021. • Costs to health care facilities and emergency facilities to revise standard operating procedures and provide training to staff, estimated to be one-time costs of \$117.2 million in 2021. • Costs to providers of air ambulance services to revise standard operating procedures and provide training to staff, estimated to be one-time costs of \$517,086 in 2021.				

• Costs to issuers and TPAs to share information related to QPA, estimated to be approximately \$55.4 million annually starting in 2022. • Costs to self-insured plans opting in to state law to include disclosure in plan documents, estimated to be one-time costs of approximately \$50,708 in 2022. • Costs to grandfathered health plans to provide the notice of right to designate a primary care provider, estimated to be \$4.5 million in 2022. • Costs to nonparticipating providers and nonparticipating emergency facilities to comply with requirements related to notice and consent, recordkeeping, and notice to plans and issuers, estimated to be one-time costs of approximately \$22.6 million in 2021 and ongoing costs of \$117.2 million annually starting in 2022. • Costs to individuals to read and understand the notice from nonparticipating providers and nonparticipating emergency facilities, estimated to be approximately \$99.1 million annually, starting in 2022. • Costs to health care providers and facilities to provide disclosures on patient protections against balance billing, estimated to be one-time costs of approximately \$6.8 million in 2021 and \$2.5 million annually starting in 2022. • Costs to states to develop state-specific language for patient disclosures to be provided by health care providers and facilities, estimated to be one-time costs of approximately \$10,732 in 2021. • Costs to health care facilities to enter into agreements for the facilities to provide the disclosure on patient protection on behalf of the providers, estimated to be one-time costs of approximately \$6.4 million in 2021. • Costs to plans and issuers to provide disclosure on patient protections to participants, beneficiaries and enrollees, estimated to be approximately \$699,245 in 2021 and approximately \$23.4 million annually starting in 2022. • Costs to individuals and providers to submit complaints related to surprise bills, estimated to be approximately \$97,452 annually starting in 2022. • Costs to the federal government to build a system to receive complaints and expand existing systems, estimated to be one-time costs of approximately \$19 million in 2021; and ongoing costs to process complaints, estimated to be approximately \$1.6 million in 2021, \$9.9 million in 2022, \$10.1 million in 2023 and \$10.3 million in 2024 and subsequent years.
Transfers:
Non-Quantified:
• Increase in health care expenditures if health care utilization increases.
Non-Quantified:
• Transfer from plans and issuers to participants, beneficiaries, and enrollees because plans and issuers will now pay additional amounts for some services provided by nonparticipating providers and facilities and participants, beneficiaries, and enrollees will experience a reduction in out-of-pocket expenditures. • Potential transfer from providers, including air ambulance providers, and facilities to the participant, beneficiary or enrollee if the out-of-network rate collected is lower than what would have been collected had the provider or facility balance billed the participant, beneficiary or enrollee.
More detailed analysis forthcoming in future rulemaking:
• Potential reduction in negotiated rates for certain health care services and air ambulance services, leading to reductions in cost sharing for individuals with health coverage. • Potential change in premiums depending on the impact on provider payments. • Potential transfer from individuals to the federal government in the form of reduced premium tax credits if premiums decrease as a result of these interim final rules. • Potential transfer from the federal government to individuals in the form of increased premium tax credits if premiums increase as a result of these interim final rules.

BILLING CODE 4120-01-C

a. Prevalence of Surprise Billing

There is extensive research on the incidence of out-of-network providers and facilities billing patients for items and services furnished at in-network

and out-of-network health care facilities. Most of these studies analyze claims data to identify cases that may potentially result in a surprise medical bill. The studies reveal that surprise billing is a significant issue for consumers across the country and

across all types of coverage. For example, an analysis of claims data from large group health plans revealed that while rates varied by state, 18 percent of emergency department visits, on average, resulted in individuals receiving a surprise medical bill in

2017. The out-of-network charges came either from facilities or providers, or both, though the majority of the charges were from individual providers, rather than facilities.¹⁰⁷ In addition, in 2017, 16 percent of inpatient stays at in-network facilities resulted in out-of-network charges, though the rate of out-of-network billing varied by state and also between rural and urban areas. Another study revealed that admissions at in-network hospitals for surgery and mental health/substance use disorders are more likely to include out-of-network charges, and women with large-employer coverage who have had a mastectomy at an in-network facility were also more likely (21 percent) to be billed for out-of-network charges.¹⁰⁸ An analysis of commercial claims data for in-network hospital admissions in 2016 found that out-of-network claims occurred in 14.5 percent of admissions, with wide variation between states.¹⁰⁹

A study using 2007–2014 claims data for group health plans indicated that in 2014, 20 percent of hospital inpatient admissions that originated in the emergency department, 14 percent of outpatient emergency department visits, and 9 percent of elective inpatient admissions were likely to result in surprise medical bills. In approximately 40 percent of inpatient admissions and more than half of outpatient cases with surprise bills, issuers paid the claims at an in-network level, so the patients were potentially billed for the remaining amount.¹¹⁰ Another study using claims data from a large issuer for the period 2010–2016 found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and that the incidence increased from 32.3 percent in 2010 to 42.8 percent in 2016. The average potential amount of the surprise medical bill also increased from \$220 in 2010 to \$628 in 2016. During the same time period, 37 percent of inpatient

admissions to in-network hospitals resulted in at least one out-of-network bill, increasing from 26.3 percent in 2010 to 42 percent in 2016 and the average potential amount of the surprise medical bill increased from \$804 to \$2,040.¹¹¹

For elective surgeries, analysis of claims data from a large issuer revealed that between 2012 and 2017, an out-of-network bill occurred in over 20 percent of cases, when the primary surgeon and facility were in-network, resulting in potential balance bills ranging from \$1,255 to \$3,449. Occurrences of out-of-network bills were associated with significantly higher total charges and out-of-pocket costs for patients, compared to cases without out-of-network bills.¹¹²

Researchers have also tried to estimate the amounts of surprise bills patients receive. A study using 2015 claims data from a large issuer for services provided at in-network hospitals concluded that average potential balance bills from anesthesiologists, pathologists, radiologists, and assistant surgeons were \$1,171, \$177, \$115, and \$7,420, respectively.¹¹³ Another study analyzing 2014–2017 data related to ambulatory surgical centers from three large issuers revealed that in 10 percent of cases, patients treated at in-network facilities received care from out-of-network providers, and patients may have received surprise bills in 8 percent of cases. On average, the amount of the surprise medical bill was \$1,141, and the amount increased by 81 percent over the period, from \$819 in 2014 to \$1,483 in 2017.¹¹⁴

Surprise billing is often associated with certain physician specialties, especially those whose services are not actively “shoppable” by consumers. Researchers analyzing claims data from a large issuer for the period 2010–2016 found that for emergency department visits, out-of-network bills arose frequently within the context of medical transport encounters (resulting in out-

of-network bills in 85.6 percent of incidents involving ambulances) and the following physician specialties: Emergency medicine (32.6 percent), anesthesiology (22.8 percent), internal medicine (23.8 percent), cardiology (20.9 percent), family practice (20.1 percent), radiology (18.1 percent), general surgery (13.3 percent), and pediatrics (8.4 percent). For inpatient admissions at in-network hospitals, in addition to medical transport (81.6 percent of cases involving ambulances), the study found that out-of-network bills arose most commonly with the following physician specialties: emergency medicine (42.6 percent of total inpatient admissions with at least 1 claim submitted by the given specialty), internal medicine (25.3 percent), radiology (22.6 percent), pathology (22.2 percent), cardiology (19.6 percent), anesthesiology (19.3 percent), family practice (18.2 percent), and obstetrics and gynecology (0.8 percent).¹¹⁵ While emergency medicine physicians make up only approximately 5 percent of the total number of active physicians,¹¹⁶ these studies show that emergency medical physicians have the highest percentage of out-of-network claims. Analysis of claims data for elective surgeries from a large issuer revealed that between 2012 and 2017, out-of-network claims were commonly associated with anesthesiologists (in 37 percent of cases), surgical assistants (37 percent), pathologists (22 percent), radiologists (7 percent), and medical consultants (3 percent).¹¹⁷ Another study analyzing commercial claims data for in-network inpatient admissions in 2016 found that some specialties with large shares of out-of-network bills were anesthesiology (16.5 percent), primary care (12.6 percent), and emergency medicine (11 percent) and that the specialties that most often billed as out-of-network at in-network facilities were independent labs (22.1 percent), followed by emergency medicine (12

¹⁰⁷ Pollitz K., et al., An examination of surprise medical bills and proposals to protect consumers from them, Peterson-KFF Health System Tracker, February 10, 2020, <https://www.healthsystemtracker.org/brief/an-examination-of-surprise-medical-bills-and-proposals-to-protect-consumers-from-them-3/>.

¹⁰⁸ Pollitz, K. et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>.

¹⁰⁹ Kennedy K. et al., Surprise out-of-network medical bills during in-network hospital admissions varied by state and medical specialty, 2016, Health Care Cost Institute, March 28, 2019, <https://healthcostinstitute.org/out-of-network-billing/oon-physician-bills-at-in-network-hospitals>.

¹¹⁰ Garmon C. and Chatock B., One In Five Inpatient Emergency Department Cases May Lead to Surprise Bills, Health Affairs 36, No. 1 (2017): 177–181.

¹¹¹ Sun E.C., Mello M.M., Moshfegh J., Baker L.C. Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. JAMA Intern Med. 2019;179(11):1543–1550. doi:10.1001/jamainternmed.2019.3451.

¹¹² Chhabra K.R. et al., Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery With In-Network Primary Surgeons and Facilities, 2020;323(6):538–547. doi:10.1001/jama.2019.21463.

¹¹³ Cooper Z. et al., Out-of-Network Billing And Negotiated Payments for Hospital-Based Physicians, Health Affairs 39, No. 1, 2020. doi: 10.1377/hlthaff.2019.00507.

¹¹⁴ Duffy E. et al., Prevalence And Characteristics Of Surprise Out-of-Network Bills from Professionals in Ambulatory Surgery Centers, Health Affairs 39, No. 5, 2020. doi:10.1377/hlthaff.2019.01138.

¹¹⁵ Sun E. et al., Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. JAMA Intern Med. 2019;179(11):1543–1550.

¹¹⁶ American Association of Medical Colleges. “Active Physicians by Age and Specialty.” Physician Specialty Data Report. (December 2019). <https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-age-and-specialty-2019>. The American Association of Medical Colleges estimated that among the 935,136 active physicians in the U.S. in 2019, 45,134 were emergency physicians (4.8%).

¹¹⁷ Chhabra K.R. et al., Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery With In-Network Primary Surgeons and Facilities, 2020;323(6):538–547. doi:10.1001/jama.2019.21463.

percent).¹¹⁸ Another study analyzing 2014–2017 data related to ambulatory surgical centers from three large issuers revealed that out-of-network bills often came from anesthesiologists (44 percent of bills), certified registered nurse anesthetists (25 percent), independent laboratories (10 percent) and pathologists (3 percent).¹¹⁹

As discussed earlier in this preamble, multiple studies have shown that a large percentage of out-of-network bills come from independent laboratories. An analysis of 2008–2016 claims data for individuals with group health insurance coverage found that there was an increase in the share of out-of-network laboratory spending, and that utilization and prices for out-of-network laboratory tests increased relative to in-network tests during that time period. The number of out-of-network laboratory tests increased by 18.9 percent each year, while the number of in-network laboratory tests increased by 2.3 percent per year. The study authors speculated that large suppliers of laboratory services have sufficient market power to set high out-of-network prices and utilization by clinicians may be influenced by financial incentives.¹²⁰

Providers who choose to remain out-of-network usually do so because it does not affect their patient volume. The ability to balance bill is often used as leverage by such providers to obtain higher in-network payments when they join plans' or issuers' networks. Higher in-network payments lead to higher premiums,¹²¹ higher cost sharing for consumers, and increased health care expenditures overall. For example, hospitals often outsource the staffing of their emergency departments to outside firms. A study on out-of-network billing in emergency departments looked at the behavior of the two largest emergency department staffing firms in the United States.¹²² The study found that one firm exits networks when it enters into a

contract with a hospital, and bills as an out-of-network provider. The other firm temporarily exits networks and later rejoins after negotiating higher in-network payments.

Utilizations of air ambulance services also frequently result in surprise bills. A study by the Government Accountability Office (GAO) analyzed private health insurance claims from 2012 and 2017 to describe the extent to which air ambulance transports are out-of-network.¹²³ This study analyzed claims data from approximately 24,100 transports in 2012 and another 33,800 transports in 2017 from all 50 states and the District of Columbia. The study found that in 2012, 75 percent of transports were out-of-network and in 2017, 69 percent were out-of-network. The GAO also reported that the median price charged by providers of air ambulance services had increased from a rate of \$22,100 for rotary-wing and \$24,900 for fixed-wing in 2012 to approximately \$36,400 for rotary-wing and \$40,600 for a fixed-wing transport in 2017. The changes in price between 2012 and 2017 indicate a consistent rate of increase as a previously published report by the GAO also noted that between 2010 and 2014, the median prices charged by providers of air ambulance services for rotary-wing transports approximately doubled.¹²⁴ Another study found that for one of the largest providers of air ambulance services (with a market share of approximately 24 percent) the average charge increased from \$17,262.23 in 2009 to approximately \$50,199.24 by 2016.¹²⁵

As the costs associated with air ambulance transports continue to increase, the GAO reported that providers of air ambulance services report entering into more network contracts.¹²⁶ However, additional analyses find that many providers of air

ambulance services, particularly those not affiliated with a hospital, do not participate in insurer networks and have little incentive to do so, further noting that network participation remains low and provider avoidance of insurance network participation combined with aggressive collection practices has been described as a business strategy of some providers of air ambulance services.¹²⁷

A study using 2014–2017 data from three large issuers to evaluate the share of air ambulance claims that are out-of-network and the prevalence and magnitude of potential surprise balance bills, found that 77 percent of air ambulance transports were out-of-network and approximately 40 percent of air ambulance transports resulted in potential balance bills. The bills averaged approximately \$19,851 in addition to the standard out-of-network cost sharing, which averaged \$561. The study also found that with out-of-network rotary-wing claims, issuers paid the providers' full billed charges approximately 48 percent of the time, at an average of \$35,733 and that for in-network providers, billed charges were paid in full only 7 percent of the time. They noted that self-insured plans paid out-of-network claims in full 50 percent of the time, whereas fully insured plans paid claims in full 38 percent of the time.¹²⁸

A study using claims data from a large issuer to evaluate the potential impact of out-of-network emergency medical transport services from 2013 to 2017 identified a total of 1,498,600 ambulance encounters of which 29,972 (2 percent) were air ambulance encounters, and of these 26,375 (88 percent) were rotary-wing and 3,597 (12 percent) were fixed-wing. The study further noted that the prevalence of potential surprise medical billing was an estimated 73 percent for rotary-wing (18,463) and 70 percent (2,518) for fixed-wing transports.¹²⁹ The study determined that the potential surprise

¹¹⁸ Kennedy K. et al., *Surprise out-of-network medical bills during in-network hospital admissions varied by state and medical specialty*, 2016, Health Care Cost Institute, March 28, 2019, <https://healthcostinstitute.org/out-of-network-billing/oon-physician-bills-at-in-network-hospitals>.

¹¹⁹ Duffy E. et al., *Prevalence And Characteristics Of Surprise Out-of-Network Bills from Professionals in Ambulatory Surgery Centers*, Health Affairs 39, No. 5, 2020. doi:10.1377/hlthaff.2019.01138.

¹²⁰ Song, Z. et al., *JAMA, Out-of-Network Laboratory Test Spending, Utilization, and Prices in the US*, JAMA. 2021;325(16):1674–1676. doi:10.1001/jama.2021.0720.

¹²¹ Duffy, E. et al., "Policies to Address Surprise Billing Can Affect Health Insurance Premiums." *The American Journal of Managed Care* 26.9 (2020): 401–404.

¹²² Cooper, Z. et al., *Surprise! Out-Of-Network Billing For Emergency Care in the United States*, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹²³ GAO (2019) Report to Congressional Committees. *Air Ambulance. Available Data Show Privately-Insured Patients Are at Financial Risk* (GAO–19–292) available at: <https://www.gao.gov/assets/700/697684.pdf>. The data analyzed included claims from over 50 payers in each year (including both fully- and self-insured plans) and accounted for 110.1 million covered lives in 2012 and 145.0 million covered lives in 2017.

¹²⁴ GAO (2017) Report to the Committee on Transportation and Infrastructure, House of Representatives. *Air Ambulance. Data Collection and Transparency Needed to Enhance DOT Oversight*. (GAO–17–637) available at: <https://www.gao.gov/assets/transportation/637637.pdf>.

¹²⁵ Consumer Union. *Up in the Air: Inadequate Regulation for Emergency Air Ambulance Transportation*. Health Policy Report, March 2017.

¹²⁶ GAO (2019) Report to Congressional Committees. *Air Ambulance. Available Data Show Privately-Insured Patients Are at Financial Risk* (GAO–19–292) available at: <https://www.gao.gov/assets/700/697684.pdf>.

¹²⁷ Missouri Department of Insurance, Financial Institutions & Professional Registration. *Policy Brief: Health Coverage for Air Ambulance Transportation*. January 2019; and New Mexico Office of the Superintendent of Insurance. *Air Ambulance Memorial Study Report*. January 2017. Available at: <https://www.nmlegis.gov/handouts/ERDT%20083117%20Item%208%20NM%20Superintendent%20of%20Insurance%20Air%20Ambulance%20Memorial%20Study%20Report.pdf>.

¹²⁸ Brown, E.C.F. et al., *Out-of-Network Air Ambulance Bills: Prevalence, Magnitude, and Policy Solutions*. *The Milbank Quarterly*, Vol. 98, No. 3, 2020 (pp. 747–774).

¹²⁹ Chhabra, H.R., McGuire, K., Scott, J.W., Nuliyalu, U., and Ryan, A. *Most Patients Undergoing Ground And Air Ambulance Transportation Receive Sizable Out-Of-Network Bills*. *Health Affairs* 39, NO. 5 (2020): 777–782.

billing amount for the study period totaled approximately \$456 million for air ambulance services, with a yearly average of \$91 million and a median potential surprise medical bill of approximately \$27,513.¹³⁰

A number of studies have reviewed state investigations or consumer complaints to obtain information on the amount of balance billing, and costs, associated with air ambulance transports. One study reviewed state investigations and found that in North Dakota, of 20 complaints against one provider of air ambulance services that charged a total of \$884,244 (an average of \$44,212 per flight), 33 percent of the charges were covered by insurance. In an additional nine states, the study found that 55 complaints resulted in a combined \$3.8 million in charges, or an average of \$77,000 per trip; and in Montana, the study found the average out-of-network rate, of the 19 bills analyzed, was \$53,397.¹³¹ The GAO further analyzed 60 consumer complaints related to air ambulance services from Maryland and North Dakota and found that from 24 complaints in Maryland the balance billed amounts ranged from \$12,300 to \$52,000 and from 36 complaints in North Dakota the balance bills ranged from \$600 to \$66,000.¹³²

b. Impact of Surprise Medical Bills

A study of out-of-network billing in emergency departments considered how some providers use the ability to bill out-of-network to increase payments. The study found that charges from out-of-network physicians in emergency departments were 637 percent of Medicare payments, which is 2.4 times higher than in-network payment rates, on average, for identical services. The study also found that emergency department physicians were paid in-network rates of 266 percent of Medicare payments, a higher percentage

of Medicare payment than most other specialists.¹³³

Another study using 2017 claims data from 3 large issuers looked at expenditures on ancillary and emergency services that are most often associated with surprise bills: emergency medicine professionals, radiologists, anesthesiologists, pathologists, emergency outpatient facilities, and emergency ground ambulance services.¹³⁴ The study concluded that a 15 percent reduction in average payments for these services would lower premiums by 1.4 percent to 1.6 percent; while a reduction in average payments to 150 percent of Medicare rates would likely lower premiums by 4.5 percent to 5.1 percent. The authors estimated that for all consumers with commercial insurance coverage, 1.6 percent and 5.1 percent reductions in premiums would result in total annual savings of \$12 billion and \$38 billion, respectively.

A study using 2015 claims data from a large issuer for services provided at in-network hospitals considered the impact of policies that would prevent anesthesiologists, pathologists, radiologists, and assistant surgeons from balance billing and would reduce their in-network payments to 164 percent of Medicare payments. The study concluded that such a reduction in payment would result in savings equal to 13.4 percent of spending on physicians and 3.4 percent of spending for people with employer-sponsored coverage, approximately \$40 billion annually.¹³⁵

Surprise bills result in higher out-of-pocket expenses and cause financial anxiety and medical debt for consumers.¹³⁶ As discussed earlier in this preamble, the impact is most keenly felt by those communities experiencing poverty and other social risk factors. Potential surprise bills can vary in size, and are often large, as concluded by the studies discussed previously. A Federal Reserve report found that about 37 percent of adults in the U.S. in 2019 would not be able to pay an unexpected

expense of \$400 using cash or its equivalent.¹³⁷ In a 2016 survey, among the respondents with health coverage who reported having difficulty paying medical bills, 75 percent reported that copayments, deductibles or coinsurance were more than they could afford and 32 percent had received out-of-network bills that insurance either did not cover or only partially covered.¹³⁸ Of those who had difficulty paying out-of-network bills, 69 percent said that it was a surprise bill and they had not been aware that the provider was out-of-network for their plan. Respondents also reported that bills from emergency room visits and hospitalizations often made up the largest share of the amount they owed. In the survey, respondents reported making sacrifices such as reducing expenditures on food, clothing, and basic household items, using up savings, working additional jobs or hours, borrowing, changing living arrangements, and reducing or delaying vacations or major household purchases. Survey respondents also reported being contacted by collection agencies. Survey results indicated that 37 percent of individuals with household incomes less than \$50,000 (compared to 14 percent with incomes of \$100,000 or more), and 47 percent of individuals with a disability (compared to 22 percent of individuals without one) had difficulties paying medical bills, demonstrating a disproportionate impact on these populations.

In addition, out-of-network cost sharing and surprise bills usually do not count towards an individual's deductible or maximum out-of-pocket expenditure limit. Therefore, individuals with surprise bills may have difficulty reaching those limits, even though they may have high health care expenses. This can result in reduced access to care, since high medical expenses can cause individuals to delay or forgo medical care. In a 2017 survey, 64 percent of respondents reported that they had delayed care in the last year because of high medical expenses and 44 percent stated that they would forgo care if their out-of-pocket expenses

¹³⁰ This study found that potential surprise bills in the study period increased from \$41 million in 2013 to \$143 million in 2017. The study further found that the median potential surprise bill from air transportation nearly doubled from \$14,356 to \$27,513, or an increase of 15 percent annually, on average, after adjustment for inflation and that the prevalence ranged from 25 percent (Minnesota) to 93 percent (Massachusetts) with the size of potential surprise bills varying widely.

¹³¹ Consumer Union. Up in the Air: Inadequate Regulation for Emergency Air Ambulance Transportation. Health Policy Report, March 2017.

¹³² GAO (2019) Report to Congressional Committees. Air Ambulance. Available Data Show Privately-Insured Patients Are at Financial Risk (GAO-19-292) available at: <https://www.gao.gov/assets/700/697684.pdf>.

¹³³ Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹³⁴ Duffy, E. et al., "Policies to Address Surprise Billing Can Affect Health Insurance Premiums." The American Journal of Managed Care 26.9 (2020): 401-404.

¹³⁵ Cooper Z. et al., Out-of-Network Billing And Negotiated Payments for Hospital-Based Physicians, Health Affairs 39, No. 1, 2020. doi: 10.1377/hlthaff.2019.00507.

¹³⁶ Garmon C. and Chatock B. One In Five Inpatient Emergency Department Cases May Lead to Surprise Bills, Health Affairs 36, No. 1 (2017): 177-181.

¹³⁷ Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2019—May 2020, <https://www.federalreserve.gov/publications/2020-economic-well-being-of-us-households-in-2019-dealing-with-unexpected-expenses.htm>.

¹³⁸ Hamel, Liz et al., The Burden of Medical Debt: Results from the Kaiser Family Foundation/New York Times Medical Bills Survey, The Henry J. Kaiser Family Foundation, 2016, <https://www.kff.org/wp-content/uploads/2016/01/8806-the-burden-of-medical-debt-results-from-the-kaiser-family-foundation-new-york-times-medical-bills-survey.pdf>.

would be more than \$500.¹³⁹ Another study reported that 7 percent of adults with health insurance delayed or went without care in 2019 because of cost reasons and adults who are in worse health are twice as likely to delay or forgo care because of cost reasons.¹⁴⁰ This study also reported that while 10.5 percent of all adults reported delaying or forgoing medical care due to costs, 15.1 percent of Hispanic adults and 13 percent of Non-Hispanic Black adults and 17.7 percent of adults with income below 200 percent of the federal poverty level reported the same, showing the disparate effect of high cost of care on these communities. Another survey concluded that 65 million adults had a health issue but did not seek treatment because of cost reasons in 2018.¹⁴¹

In addition to causing financial hardship, surprise medical bills may also cause consumers to change providers in the future. Analysis of a large national sample of claims for obstetrics patients who had two deliveries covered by insurance found that 11 percent of patients received a surprise medical bill for their first delivery and were 13 percent more likely to switch hospitals for the second delivery compared to patients who did not.¹⁴²

Individuals living in rural areas experience socioeconomic and health related disparities.¹⁴³ Rural areas have fewer primary care and mental health providers and higher rates of preventable hospitalizations. Currently, there are 1,805 rural hospitals in the United States,¹⁴⁴ with 137 rural hospitals having closed since 2010.¹⁴⁵ Individuals who live in rural or geographically remote areas often must rely on air ambulance services for

transfer to facilities with equipment and expertise to treat serious medical conditions. Often these transports are costly due to lack of options for in-network providers available to provide lifesaving services.¹⁴⁶ It is estimated that a quarter of Americans, approximately 85 million people, are unable to access health care in less than an hour of travel time without an air ambulance, and air ambulances may be the only viable means of transporting patients to the health care center they need.¹⁴⁷ One air ambulance provider estimates that 90 percent of their transports originate from rural areas, a defined by CMS.¹⁴⁸ The GAO found that about 60 percent of rotary-wing bases added between 2012 and 2017 were located in rural areas, and about half of fixed-wing bases added between 2012 and 2017 were rural.¹⁴⁹ As a result of the growing reliance on air ambulance services, rural populations are disproportionately affected by high costs of air ambulance services.

c. Existing State Laws Regarding Balance Billing

As of February 5, 2021, 33 states have enacted legislation that provides some protection for consumers with regard to balance bills.¹⁵⁰ Laws vary by state; there are differences in the types of networks, plans, facilities, and providers that are subject to regulations, and in payment standards. While most of these states prohibit balance billing for emergency services, many of them also prohibit balance billing for certain non-emergency care furnished at in-network hospitals. It is possible that states may enact new legislation or modify existing legislation in response to the passage of the No Surprises Act and these implementing regulations.

Even within a state that has enacted such protections, those protections typically apply only to individuals enrolled in group or individual health

insurance coverage, as ERISA generally preempts state laws that regulate self-insured group health plans sponsored by private employers. (Some state laws allow ERISA-covered plans to opt in to the consumer protections and process for setting payment under the state law.) In addition, states are limited in their ability to address surprise bills that involve out-of-state providers.

The air ambulance industry currently functions and operates within the health care system unlike any other entity or service, only somewhat due to the unique nature of the service. There are limited avenues for states and the U.S. Department of Transportation (DOT) to regulate their operations. States and the DOT have limited authority under the ADA to regulate the prices, routes, or services of an air carrier, including an air ambulance operator, in air transportation.¹⁵¹ The intent of the ADA was to allow the prices of air transportation services to be controlled by market forces.¹⁵² The ADA defines an “air carrier” as “a citizen of the United States undertaking by any means, directly or indirectly, to provide air transportation;” defining “air transportation” to include interstate air transportation.¹⁵³ The ADA effectively limits the ability of states to regulate the prices, routes, or services of air carriers that provide transportation services,¹⁵⁴ explicitly stating that states “may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier that may provide air transportation.”¹⁵⁵ The Departments are not aware of any state laws regulating or limiting surprise billing or other price control measures with regard to air ambulance providers or the air ambulance industry.

State laws appear to have succeeded in providing some protection to consumers from balance billing. A study analyzing the impact of New York State’s law concluded that the law resulted in a 34 percent reduction in surprise billing in the state and lowered in-network emergency department physician payments by 9 percent.¹⁵⁶ In

¹³⁹ Heath, Sara, 64% of Patients Avoid Care Due to High Patient Healthcare Costs, Patient Engagement HIT, 2018, <https://patientengagementhit.com/news/64-of-patients-avoid-care-due-to-of-high-patient-healthcare-costs>.

¹⁴⁰ Amin, K. et al., How Does Cost Affect Access to Care?, Peterson-KFF Health System Tracker, January 5, 2021, <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start>.

¹⁴¹ Gallup and West Health, The U.S. Healthcare Cost Crisis, 2019, <https://news.gallup.com/poll/248081/westhealth-gallup-us-healthcare-cost-crisis.aspx>.

¹⁴² Chartock, B. et al., Consumers’ Responses to Surprise Medical Bills in Elective Situations, Health Affairs 38, No. 3 (2019): 425–430.

¹⁴³ North Carolina Rural Health Research Program, Rural Health Snapshot (2017), May 2017, https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/05/Snapshot2017.pdf.

¹⁴⁴ American Hospital Association, Fast Facts on U.S. Hospitals, 2021, <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁴⁵ Cecil G. Sheps Center for Health Services Research, UNC, Rural Hospital Closures, <https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>.

¹⁴⁶ Haer, A., Senate Bill 1264: The Texan Template for the National Fight Against Balance Billing, Texas Law Review, 99(4), 813–838 (2021).

¹⁴⁷ Hinsdale, J.G. Report of the Council on Medical Services: Air Ambulance Regulations and Payments. American Medical Association. (2018), available at: <https://www.ama-assn.org/system/files/2018-12/i18-cms-report2.pdf>.

¹⁴⁸ Air Evac Lifeteam, <https://lifeteam.net/history-and-mission/#:-text=Approximately%2090%20percent%20of%20Air,are%20based%20in%20rural%20areas>.

¹⁴⁹ GAO (2019) Report to Congressional Committees. Air Ambulance. Available Data Show Privately-Insured Patients Are at Financial Risk (GAO–19–292), available at: <https://www.gao.gov/assets/700/697684.pdf>.

¹⁵⁰ The Commonwealth Fund, State Balance-billing Protections, https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.

¹⁵¹ See <https://www.transportation.gov/individuals/aviation-consumer-protection/air-ambulance-service>.

¹⁵² Missouri Department of Insurance, Financial Institutions & Professional Registration, Policy Brief: Health Coverage for Air Ambulance Transportation, January 2019.

¹⁵³ 49 U.S.C. 40102.

¹⁵⁴ 49 U.S.C. 41713.

¹⁵⁵ 49 U.S.C. 41713(b).

¹⁵⁶ Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

addition, between the implementation of the law in March 2015 and the end of 2018, the law saved individuals in the state over \$400 million with respect to emergency services.¹⁵⁷ These savings were partly due to a reduction in costs associated with emergency services and a greater incentive to participate in provider networks. In New Jersey, issuers experienced a reduction in costs associated with emergency and inadvertent out-of-network claims since the state law took effect.¹⁵⁸ The total spending on involuntary out-of-network services were reduced by 56 percent for issuers in the individual market and by 38 percent for the issuers in the small group market. A report on California law concluded that patients were being protected from surprise medical bills in the state and that issuers had broader networks such that 80 percent to 100 percent of their hospitals and health care facilities had no nonparticipating providers practicing there.¹⁵⁹ A study on the impact of California's surprise billing law analyzed claims data for provider specialties most affected by the law (anesthesiology, diagnostic radiology, pathology, assistant surgeons, and neonatal-perinatal medicine) for the pre-implementation period from January 2014 to June 2017 and the post-implementation period from July 2017 to December 2018.¹⁶⁰ The study concluded that the share of services delivered out-of-network by the affected specialties at inpatient hospitals and ambulatory surgical centers decreased by 17 percent, ranging from a 15 percent reduction for pathology to a 31 percent decline for neonatal-perinatal medicine.

d. Benefits

Provisions in these interim final rules will protect participants, beneficiaries, or enrollees with health coverage from

receiving surprise bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances. Providers will no longer be able to balance bill an individual for emergency services. A provider will only be able to balance bill an individual for certain post-stabilization services, and for services performed by nonparticipating providers at certain participating facilities, if the provider or facility provides notice to the participant, beneficiary, or enrollee, and obtains the individual's consent to receive care on an out-of-network basis and be balance billed. Further, provisions ensuring all relevant civil rights protections are upheld and communication with consumers is accessible, in a language that is understandable, and at an appropriate literacy level, help to effectively confer these protections to minority and underserved communities.

These interim final rules also specify that for emergency services furnished by a nonparticipating provider or emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the statute and in these interim final rules, while for nonparticipating providers of air ambulance services, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the billed amount or QPA, as defined by the statute and in these interim final rules.

In addition, these interim final rules require that these cost-sharing amounts be counted toward any in-network deductible or in-network out-of-pocket maximums applied under the plan or coverage in the same manner as if such cost-sharing payments were made with respect to services furnished by a participating provider, participating facility, or participating provider of air ambulance services.

Consider, for example, one case included in the project by Vox,¹⁶¹ where

a victim of a violent attack was taken to an emergency facility. When the individual was able, he checked to make sure that the hospital was in-network for his plan. He was not aware, however, that the surgeon who performed emergency jaw surgery was nonparticipating for his plan and the individual received a surprise bill of \$7,924. Two other cases in the same study included an individual involved in a bike crash and another individual hit by a public bus. Both individuals were treated at the same emergency facility, which was out-of-network for both their plans and received surprise bills of \$20,243 and \$27,660, respectively. In another case, the parents of an infant who needed an inter-facility air ambulance transport for urgent surgery received a surprise medical bill of approximately \$64,000 from the air ambulance provider.¹⁶² Another case reported in the media¹⁶³ involved an expectant mother choosing an in-network hospital and a participating obstetrician for the birth of her baby. However, a nonparticipating pediatrician was called in due to a potential risk of post-delivery complications for the baby. The mother later received a surprise bill of \$636 from the pediatrician because her plan had denied the claim. In each of these situations, plans and issuers either denied the claim or paid the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services an amount that the plan or issuer considered reasonable for the services provided, and the nonparticipating provider or nonparticipating facility sent a balance bill to the individual. Under the No Surprises Act and these interim final rules, individuals in similar situations will only be responsible for in-network cost-sharing amounts and deductibles. Nonparticipating providers and nonparticipating facilities will not be able to balance bill such individuals, but instead will need to agree to an amount of payment with plans and issuers or enter into the independent dispute resolution process to determine an appropriate payment amount, if

¹⁵⁷ New York State Department of Financial Services. New York's Surprise Out-of-Network Protection Law: Report on the Independent Dispute Resolution Process. September 2019.

¹⁵⁸ State of New Jersey Department of Banking and Insurance. The Out-of-network Consumer Protection, Transparency, Cost Containment, and Accountability Act (Pub. L. 2018, c. 32) Data Reporting. As of January 31, 2021. https://www.state.nj.us/dobi/division_insurance/oonarbitration/data/210131report.html.

¹⁵⁹ Health Access California. Patients Protected, Providers Paid: Data From Three Years of California's Compromise to Stop Surprise Medical Bills. September 2019. <https://health-access.org/wp-content/uploads/2019/09/ha-factsheet-AB72report-final.pdf>.

¹⁶⁰ Adler, L. et al. California Saw Reduction In Out-Of-Network Care From Affected Specialties After 2017 Surprise Billing law. U.S.C.-Brookings Schaeffer Initiative for Health Policy, September 26, 2019. <https://www.brookings.edu/blog/uscbrookings-schaeffer-on-health-policy/2019/09/26/california-saw-reduction-in-out-of-network-care-from-affected-specialties-after-2017-surprise-billing-law/>.

¹⁶¹ Kliff S. Surprise medical bills, the high cost of emergency department care, and the effects on patients [published online August 12, 2019]. *JAMA Intern Med.* doi:10.1001/jamainternmed.2019.3448.

¹⁶² Wingerter, Megan. \$64K Air Ambulance Tab Shows Limits of Surprise Billing Law. *Claims Journal.* January 4, 2021. <https://www.claimsjournal.com/news/national/2021/01/04/301271.htm>.

¹⁶³ Herman, Bob. Billing squeeze: Hospitals in middle as insurers and doctors battle over out-of-network charges. *Modern Healthcare.* August 29, 2015. <https://www.modernhealthcare.com/article/20150829/MAGAZINE/308299987/billing-squeeze-hospitals-in-middle-as-insurers-and-doctors-battle-over-out-of-network-charges>.

agreement on a payment amount cannot be reached.

Therefore, individuals with health coverage, including members of minority and underserved communities, are likely to see a significant reduction in balance billing, reducing one source of anxiety, financial stress, and medical debt. They will also experience a reduction in out-of-pocket expenditures, because they will only be liable for their in-network cost-sharing amounts when receiving care from nonparticipating providers, emergency facilities, and providers of air ambulance services, which will now count towards their deductible and maximum out-of-pocket limits, allowing individuals to reach those limits sooner. As discussed previously in this preamble, a significant number of individuals forgo or delay care due to the cost of care. A reduction in out-of-pocket expenses is likely to improve access to care and allow individuals to obtain needed treatment that they may otherwise have neglected or foregone due to concerns about the cost of care.

These interim final rules also establish a complaints process for receiving and resolving complaints related to these new surprise billing protections. The Departments are of the view that this will result in increased compliance with balance billing requirements and ensure that all individuals, including members of minority and underserved communities, are able to benefit from the protections provided by the No Surprises Act and these interim final rules. The Departments also seek comment from members of minority and underserved communities to help identify barriers to individuals exercising their rights under the No Surprises Act, as well as policies to address and remove such barriers.

The No Surprises Act extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. Participants, beneficiaries, and enrollees in grandfathered plans will now be able to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. If patients are able to choose physicians they trust and with whom they have a good relationship, they are likely to have better health outcomes.¹⁶⁴ Similarly, allowing physicians specializing in pediatrics to become primary care physicians for children will also improve health outcomes for

children. The American Academy of Pediatrics (AAP) strongly supports the idea that the choice of primary care clinicians for children should include pediatricians.¹⁶⁵ In addition, a female participant, beneficiary, or enrollee in a grandfathered plan who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology will not need an authorization or referral by the plan, issuer, or any person (including a primary care provider), which will allow them to obtain care without any delay.

The potential financial savings to consumers as a result of the protections in these interim final rules are significant. As of January 1, 2022, individuals across the country will no longer receive surprise medical bills for out-of-network emergency services, non-emergency services provided by nonparticipating providers at certain participating health care facilities, or air ambulance services. The Departments understand that some of these savings will result instead in cost transfers from participants, beneficiaries, and enrollees to group health plans or issuers, as discussed later in this preamble, or may ultimately be paid for by individuals in the form of increased health insurance premiums, which will be discussed in future rulemaking. However, the Departments anticipate that there are potentially additional cost savings for individuals, but are unaware of comprehensive national data that quantifies the potential financial benefits to individuals of the surprise billing protections included in these rules and invite stakeholders to share relevant data that would help the Departments quantify this potential consumer financial benefit.

e. Costs

Plans, issuers, health care providers, facilities, and providers of air ambulance services will incur significant costs to comply with the requirements of these interim final rules.

These interim final rules specify that for emergency services furnished by a nonparticipating provider or emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been

charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the No Surprises Act and these interim final rules. For nonparticipating providers of air ambulance services, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the billed amount or the QPA, as defined by the statute and in these interim final rules. In addition, these interim final rules require that such cost sharing must also be counted toward any in-network deductible or in-network out-of-pocket maximums applied under the plan or coverage in the same manner as if such cost sharing payments were made with respect to services furnished by a participating provider, a participating facility, or a participating provider of air ambulance services.

Under these interim final rules, cost-sharing for emergency services furnished by a nonparticipating provider or emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, must be calculated based on the “recognized amount,” which is: (1) An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act, (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law, or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed amount for the services or the QPA, which generally is the median of the contracted rates of the plan or issuer for the item or service furnished in the applicable geographic region. For air ambulance services, subject to these interim final rules, plans and issuers generally must use the QPA to calculate cost sharing.

Plans and issuers will incur significant costs to calculate the recognized amount and applicable cost-sharing amount. The Departments assume that for self-insured group health plans, the costs will be incurred by third party administrators (TPAs). The Departments estimate a total 1,758 entities—1,553 issuers¹⁶⁶ and 205

¹⁶⁴ Olaisen, R., et al., “Assessing the Longitudinal Impact of Physician-Patient Relationship on Functional Health.” *The 18 Annals of Family Medicine* 5 (2020). <https://www.annfammed.org/content/18/5/422>.

¹⁶⁵ See AAP Policy Statement, “Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults”. <https://pediatrics.aappublications.org/content/pediatrics/132/5/e1452.full.pdf>.

¹⁶⁶ Based on data from MLR annual report for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

TPAs¹⁶⁷—will be required to comply with these interim final rules with regard to calculating the QPA and to calculate an individual's cost sharing liability. The Departments anticipate that issuers and TPAs will need to make changes to their information technology (IT) systems to include the capability to calculate the QPA for all out-of-network claims subject to the surprise billing protections, or the amount determined by state law or All-Payer Model Agreement, if applicable, and provide the required information related to the QPA to nonparticipating providers and nonparticipating emergency facilities. In addition, system changes will be necessary to accept and process out-of-

network claims, calculate the appropriate cost-sharing amounts and include them in deductible and out-of-pocket maximum limits. The one-time cost to make system changes to include these new functionalities may be slightly lower for plans (or TPAs) and issuers already subject to state balance billing laws. The Departments estimate that each plan (or TPA) or issuer will incur one-time costs of approximately \$2.8 million, on average, to make the necessary system changes to automate the process. The total costs for all plans (or TPAs) and issuers will be approximately \$4,958 million. The Departments assume that these one-time costs will be incurred in 2021. In

addition, each issuer or TPA will incur ongoing costs related to system maintenance, processing out-of-network claims and to acquire external data necessary to calculate the QPA when there is insufficient information to calculate median contracted rates starting in 2022. The Departments estimate each issuer or TPA will incur, on average, ongoing costs of \$1.2 million in 2022 and approximately \$411,840 annually starting in 2023. The total annual costs for all issuers and TPAs will be \$2,047 million in 2022 and \$724 million annually starting in 2023. See Tables 2 and 3 for more details. The Departments seek comment on these estimates.

TABLE 2—ONE-TIME IT COSTS RELATED COSTS FOR PLANS AND ISSUERS IN 2021

Occupation:	Hourly wage rate	2021	
		Time (hours)	Estimated labor cost
IT Costs			
Project Manager/Team Lead	\$110.00	2,080	\$228,800
Scrum Master	110.00	3,640	400,400
Senior Business Analysis	134.00	1,560	209,040
UX Researcher/Service Designer	129.00	2,080	268,320
Technical Architect/Sr. Developer	207.00	2,080	430,560
DevOps Engineer/Security Engineer	143.00	1,560	223,080
Application Developer	111.00	9,360	1,038,960
Total IT Costs for Each Issuer or TPA		22,360	2,799,160
Total IT Costs for all Issuers and TPAs		39,308,880	4,920,923,280
Management Costs			
Chief Executives	190.24	80	15,219
Lawyers	143.18	40	5,727
Total		120	20,946
Total Management Costs for all plans and issuers		210,960	36,823,771
Total Costs for all Issuers and TPAs		39,519,840	4,957,747,051

Note: All wage rates except those related to management costs use the Contract Awarded Labor Category (CALC) tool.¹⁶⁸ Wage rates for management costs are derived using data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead).¹⁶⁹

TABLE 3—ONGOING ANNUAL OPERATIONAL COSTS FOR ISSUERS AND TPAs STARTING IN 2022

Occupation:	Hourly wage rate	2022		2023 onwards	
		Time (hours)	Estimated labor cost	Time (hours)	Estimated labor cost
Project Manager/Team Lead	\$110.00	1,040	\$114,400	520	\$57,200
Scrum Master	110.00	1,300	143,000	520	57,200
Senior Business Analysis	134.00	780	104,520	0	0
UX Researcher/Service Designer	129.00	780	100,620	0	0
Technical Architect/Sr. Developer	207.00	1,040	215,280	520	107,640
DevOps Engineer/Security Engineer	143.00	780	111,540	520	74,360
Application Developer	111.00	3,380	375,180	1,040	115,440
Total for Each Plan or Issuer		9,100	1,164,540	3,120	411,840

¹⁶⁷ Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

¹⁶⁸ The CALC tool (<https://calc.gsa.gov/>) was built to assist acquisition professionals with market

research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. Wages obtained from the CALC database are fully burdened to account for fringe benefits and overhead costs.

¹⁶⁹ See May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates, available at https://www.bls.gov/oes/current/oes_nat.htm.

TABLE 3—ONGOING ANNUAL OPERATIONAL COSTS FOR ISSUERS AND TPAS STARTING IN 2022—Continued

Occupation:	Hourly wage rate	2022		2023 onwards	
		Time (hours)	Estimated labor cost	Time (hours)	Estimated labor cost
Total Costs for all Issuers and TPAs		15,997,800	2,047,261,320	5,484,960	724,014,720

Issuers and TPAs will also need to revise their standard operating procedures to include processes related to out-of-network claims, recognized amount and QPA, and provide training to their billing personnel and customer service representatives. The Departments assume that, for each issuer or TPA, a business operations specialist will need 40 hours (at an hourly labor cost of \$81.06) and a senior manager (at an hourly labor cost of \$114.24) will need 16 hours to revise the standard operating procedures, with a total cost of approximately \$5,070. In addition, the Departments assume that, on average, 10 staff at each issuer and TPA will receive 4 hours of training at a cost of \$1,824. For all 1,758 issuers and TPAs, the total cost of revising standard operating procedures and training will be \$12.1 million. The Departments assume that these one-time costs will be incurred in 2021 and that new staff will be trained as a part of the usual on-boarding process at minimal additional cost and burden.

Health care and emergency facilities will also incur costs to revise their standard operating procedures and provide training to their staff regarding notice and consent requirements, patient disclosures, and out-of-network billing. The Departments estimate that there are 16,992 emergency and health care facilities (6,090 hospitals,¹⁷⁰ 270 independent freestanding emergency departments,¹⁷¹ 9,280 ambulatory surgical centers,¹⁷² and 1,352 critical access hospitals) that will incur this cost. The Departments assume that for hospital-affiliated freestanding emergency departments, the disclosure will be developed by the parent hospitals. The Departments estimate that, on average, for each health care facility, a business operations specialist

will need 40 hours and a senior manager will need 16 hours to revise the standard operating procedures, with a total cost of approximately \$5,070. In addition, on average, 10 staff at each hospital will receive 4 hours of training at a cost of approximately \$1,824. This estimate is an average of the costs and burden to be incurred by each health care facility and the Departments recognize that the costs and burden may vary depending on the size of each health care facility. The total one-time cost for 16,992 health care facilities is estimated to be approximately \$117.2 million, to be incurred in 2021, with the expectation that new staff will be trained as a part of the usual on-boarding process at minimal additional cost and burden.

Providers of air ambulance services will also incur costs to revise their standard operating procedures and provide training to their staff regarding out-of-network billing. The Departments assume that for each air ambulance provider, a business operations specialist will need 40 hours and a senior manager will need 16 hours to revise the standard operating procedures, with a total cost of approximately \$5,070. In addition, on average, 10 staff for each provider will receive 4 hours of training at a cost of approximately \$1,824. The total on-time cost for each provider of air ambulance services will be approximately \$6,894 in 2021. The total one-time cost for 75 providers of air ambulance services¹⁷³ is estimated to be approximately \$517,086, to be incurred in 2021, with the expectation that new staff will be trained as a part of the usual on-boarding process at minimal additional cost and burden.

The Departments estimate that grandfathered plans and issuers will incur a total cost of approximately \$4,516,225 in 2022 to provide the notice of right to designate a primary care provider to participants, beneficiaries, and enrollees. Self-insured plans opting in to state law will incur one-time costs of \$50,708 in 2022 to include a disclosure in plan documents. TPAs and

issuers will also incur costs of approximately \$55.4 million annually to share information related to QPAs with nonparticipating providers, nonparticipating emergency facilities, and nonparticipating providers of air ambulance services. Additionally, issuers and TPAs will incur costs to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits the disclosure regarding patient protections against balance billing. The Departments estimate a one-time cost, incurred in 2021, for all issuers and TPAs to be \$699,245 and ongoing annual costs, to begin in 2022, of approximately \$23.4 million. These costs are discussed in detail in the Paperwork Reduction Act section of this preamble.

Nonparticipating providers and nonparticipating emergency facilities may balance bill a participant, beneficiary, or enrollee if certain notice and consent requirements have been met. Providers and facilities will incur costs to prepare the notice, provide notice and receive consent from patients, retain records, and provide notice to plans and issuers. HHS estimates that the one-time cost to prepare the notice and consent documents will be approximately \$22.6 million in 2021. The ongoing annual cost to provide the notice and obtain consent, retain records and provide notice to plans and issuers is estimated to be approximately \$117.2 million starting in 2022. In addition, individuals receiving the notice and consent, where applicable, will incur costs of approximately \$99.1 million annually, starting in 2022, to read and understand the notice. These costs are discussed in detail in the Paperwork Reduction Act section of this preamble.

Health care providers and facilities will also incur costs to make publicly available, post on a public website of the provider or facility, and provide to participants, beneficiaries, and enrollees a one-page notice disclosure on patient protections against surprise billing and for providers and facilities to enter into agreements for the facilities to provide the disclosure on behalf of the providers. HHS estimates the one-time total cost, to be incurred in 2021, to be

¹⁷⁰ American Hospital Association, Fast Facts on U.S. Hospitals, 2021. Available at <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁷¹ Emergency Medicine Network, 2018 National Emergency Department Inventory—USA. Available at <https://www.emnet-usa.org/research/studies/medi/medi2018/>.

¹⁷² Moriarty, A., Definitive Healthcare, How Many Ambulatory Surgery Centers are in the US?. Blog. April 10, 2019. Available at: <https://blog.definitivehc.com/how-many-ascs-are-in-the-us#:-:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers>.

¹⁷³ Federal Aviation Administration, Fact Sheet—FAA Initiatives to Improve Air Ambulance Safety, 2014, https://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=15794.

approximately \$13.1 million and the ongoing annual cost, to begin in 2022, to be approximately \$2.5 million. HHS encourages states to develop language to assist facilities in fulfilling this disclosure requirement as it applies to disclosing state protections against balance billing. HHS estimates that the 33 states that currently have legislation to provide some protection to consumers for surprise billing will incur one-time costs of approximately \$10,732 in 2021 to develop the model language. These costs are discussed in detail in the Paperwork Reduction Act section of this preamble.

The No Surprises Act directs the Departments to establish a process to receive complaints regarding violations of the application of the QPA by group health plans and health insurance issuers offering group or individual health coverage. Individuals and entities that submit a complaint related to surprise billing will also incur costs to do so. As discussed in the Paperwork Reduction Act section of the preamble, the Departments estimate related costs to be approximately \$97,452 annually starting in 2022. In addition, the federal government will incur a one-time cost of approximately \$16 million in 2021 to build the IT system to receive and process complaints, an additional \$3 million to update existing systems in 2021, and ongoing annual costs of approximately \$1.6 million in 2021, \$9.9 million in 2022, \$10.1 million in 2023 and \$10.3 million in 2024 and subsequent years to process the complaints received and for system maintenance.

As discussed previously, individuals with protections against surprise billing are likely to experience a reduction in out-of-pocket expenses. This may increase their use of health care, which could lead to an increase in health care expenditures overall.

The Departments seek comment on these estimates and also on any additional costs incurred by plans, issuers, providers, and facilities.

f. Transfers

The provisions in these interim final rules will result in lower out-of-pocket spending by individuals. In situations where surprise bills currently occur, participants, beneficiaries, and enrollees will be responsible for only an approximation of the cost-sharing amounts they would have paid had the services been provided by a participating emergency facility, participating provider, or participating provider of air ambulance services. Plans and issuers will now be required to pay for some expenses for items and

services provided by nonparticipating facilities, providers, and providers of air ambulance services that they previously did not pay for. Thus, expenditures will shift from certain individuals to plans and issuers. In addition, it is possible the out-of-network rates collected by some providers, including air ambulance providers, and facilities will be lower than they would have been if the providers and facilities were able to balance bill the individuals. Such situations will result in transfers from providers and facilities to individuals. If there is a decrease in payments to some participating providers, as has happened for in-network emergency department physician payments in the state of New York,¹⁷⁴ there will be a transfer from those providers to plans, issuers, participants, beneficiaries, and enrollees.

As discussed previously in this preamble, these interim final rules are the first of several rules implementing the No Surprises Act and the transparency provisions of title II of Division BB of the CAA. Later this year, the Departments intend to issue additional regulations including regulations regarding the federal IDR process. The impact of the provisions of the No Surprises Act on premiums will depend on provisions not included in these interim final rules, and more detailed analysis will therefore be included in future rulemaking.¹⁷⁵

C. Regulatory Alternatives

In developing the interim final rules, the Departments considered various alternative approaches.

Determining the Cost-sharing Amount. The No Surprises Act generally requires that cost sharing for items and services subject to the surprise billing protections be based on the recognized amount. In instances where this requirement applies, the Departments considered whether it should apply where the billed charge is less than the recognized amount. In these instances, assuming the plan or issuer would not pay more than the billed charge, calculating cost sharing based on the QPA (which is one way in which the recognized amount might be

determined) would require a participant, beneficiary, or enrollee to pay a higher percentage in cost sharing than if such items or services had been furnished by a participating provider. However, sections 9816(a)(1)(C)(ii) and 9816(b)(1)(A) of the Code, sections 716(a)(1)(C)(ii) and 716(b)(1)(A) of ERISA, and sections 2799A–1(a)(1)(C)(ii) and 2799A–1(b)(1)(A) of the PHS Act expressly prohibit plans and issuers from applying a cost-sharing requirement that is greater than the requirement that would apply if services were provided by a participating provider or a participating emergency facility. Therefore, under these interim final rules, in circumstances where an All-Payer Model Agreement or specified state law does not apply to determine the recognized amount, cost sharing must be based on the lesser of the QPA or the amount billed by the provider for the item or service.

Methodology for Calculating the QPA.

The No Surprises Act generally requires the QPA to be calculated based on the median of the contracted rates of the plan or issuer. The Departments considered whether plans and issuers should take into account the number of claims paid at the contracted rate under each contract in calculating the QPA. Doing so, however, would not result in a pure median of the contracted rates, which the Departments are of the view would most clearly follow the language of the No Surprises Act. In addition, the Departments are of the view that this approach would likely put upward pressure on the QPA, by giving greater weight to contracts of larger provider groups and facilities, which are more likely to have negotiated higher rates than small provider groups and facilities. This approach could lead to higher out-of-pocket costs for individuals.

The Departments also considered requiring plans and issuers to calculate separate median contracted rates for facilities based on the characteristics of facilities, such as by distinguishing teaching hospitals from non-teaching hospitals, rather than distinguishing only on the basis of whether the facility is an emergency department of a hospital or an independent freestanding emergency department. The Departments decided against this approach, as doing so would result in a higher median contracted rate for facilities with higher operating costs and is not clearly contemplated in the definition of QPA under the No Surprises Act. The Departments are of the view that the different operating costs among facilities with different characteristics should not have such a

¹⁷⁴ Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹⁷⁵ These interim final rules and the forthcoming regulations are interrelated, and in cases such as this, attribution of impacts is challenging. Inclusion of more detailed analysis in later rulemaking, rather than these interim final rules—about, for example, changes in premiums incentivized by the suite of surprise billing policies—should not be interpreted as indicating certainty that such impacts will not occur as a result of these interim final rules.

dramatic impact on median contracted rates. However, the Departments recognize that payment amounts for facility charges may vary depending on whether an emergency facility is connected with a hospital. Therefore, the interim final rules allow separate median contracted rates to be calculated for emergency services based on whether the facility is an emergency department of a hospital or an independent freestanding emergency department.

With respect to calculating a separate QPA for each item and service for each geographic region, the Departments considered whether to define each geographic region as the applicable rating area as defined for purposes of the individual and small group market rating rules under PHS Act 2701 section and 45 CFR 147.102, while allowing states the flexibility to establish alternative geographic regions. However, some states define rating area by county, resulting in large numbers of rating areas in a state, some of which might include few, if any, facilities and providers. Therefore, adopting rating area as the standard for geographic region could lead to a large number of geographic regions for which a plan or issuer would have to calculate separate median contracted rates, a large number of geographic regions without sufficient information, as well as a large number of geographic regions in which the median contracted rate is influenced by outliers. Therefore, the interim final rules do not adopt this approach to defining geographic regions.

With respect to the statutory requirement for plans and issuers to calculate separate QPAs for each insurance market, including for self-insured group health plans, the Departments considered whether the market for self-insured group health plans should be limited to only self-insured group health plans offered by the same plan sponsor. However, this could lead to greater instances of a self-insured plan lacking sufficient information, so the interim final rules instead define the self-insured market as all self-insured group health plans offered by the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity that is responsible for determining the QPA on behalf of the plan (including a third-party administrator contracted by the plan).

Participant, Beneficiary, and Enrollee Responsibility to Pay Recognized Amount Only. In instances where a participant, beneficiary, or enrollee has not satisfied their deductible, the

Departments considered whether the plan or issuer should not be required to pay any portion of the out-of-network rate to the nonparticipating provider or facility. However, these interim final rules require that when the out-of-network rate exceeds the recognized amount (the amount upon which cost sharing is based), a plan or issuer must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount (the latter of which in this case would equal the recognized amount), even in instances where an individual has not satisfied their deductible. This approach is consistent with the purpose of the No Surprises Act to protect participants, beneficiaries, or enrollees from surprise balance bills that exceed in-network cost-sharing requirements. This approach is also consistent with section 102 of the No Surprises Act, which amends section 223 of the Code to specify that these payments will not prevent a plan from qualifying as a high-deductible health plan or make an individual ineligible to contribute to a health savings account.

Definition of Health Care Facility. The No Surprises Act defines a health care facility as each of the following with respect to non-emergency services: (1) A hospital (as defined in 1861(e) of the Social Security Act); (2) a hospital outpatient department; (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act; or (5) any other facility, specified by the Departments, that provides items or services for which coverage is provided under the plan or coverage, respectively. The Departments considered whether to expand the definition of health care facility in this rulemaking, but concluded that the facilities at which balance billing are currently most frequent are included in the current definition. The Departments anticipate continuing to monitor the prevalence of surprise billing at various facilities and may expand the definition in future rulemaking. In particular, as discussed earlier in this preamble, the Departments considered including urgent care centers in the definition of health care facility. However, given the variation across states in how urgent care centers are licensed, including the scope of services that the centers are permitted to provide, the Departments decided to instead seek comment regarding whether the definition of health care facility should be extended to urgent care centers, including those

that are not licensed as facilities under state law.

With respect to the definition of participating health care facility and participating emergency facility, the Departments considered excluding facilities that had only single case agreements in place with a plan or issuer. However, the Departments are persuaded that doing so could harm participants, beneficiaries or enrollees. When individuals are provided with care, generally non-emergency items or services, under a single case agreement, they should not have to worry about potential surprise bills. Excluding facilities with single case agreements from the definitions of participating facilities and participating emergency facilities would be inconsistent with the Departments' intent to protect individuals from surprise medical bills.

Applicability of State Law. In determining how state laws around balance billing would intersect with the No Surprises Act, the Departments considered alternatives to the approach taken under these interim final rules, which seek to supplement, rather than supplant state balance billing laws. Specifically, the Departments considered whether to allow states to be more protective of consumers than the No Surprises Act with respect to whether individuals are permitted to waive balance billing protections upon notice and consent, and concluded that it is in the public interest to interpret the No Surprises Act as creating a floor regarding individuals' ability to waive balance billing protections. The Departments also considered whether state provisions allowing ERISA-covered plans to opt in to the state requirements should be considered specified state laws for purposes of setting the recognized amount and out-of-network rate regarding ERISA-covered plans that have opted into the state programs. The Departments have concluded such deference to state law is consistent with the overarching structure of the No Surprises Act. The Departments also considered allowing providers, facilities and providers of air ambulance services to opt in to state laws (as allowed under state laws), but decided to instead seek comments on this approach, as discussed earlier in this preamble.

Notice and Consent Exception to Prohibition on Balance Billing. Under the No Surprises Act and these interim final rules, the protections that limit cost sharing and prohibit balance billing do not apply to certain non-emergency services or to certain post-stabilization services provided in the context of emergency care, if the nonparticipating

provider or nonparticipating emergency facility furnishing those items or services provides the participant, beneficiary, or enrollee, with certain notice, the individual acknowledges receipt of the information in the notice, and the individual consents to be treated by the nonparticipating emergency facility or nonparticipating provider. These interim final rules establish the conditions under which notice and consent may be provided for certain non-emergency and post-stabilization services. The Departments considered a number of additional conditions under which the notice and consent exception would not be permitted, such as if the individual were experiencing pain, or under the influence of alcohol or drugs, including the use or administration of prescribed medications. The Departments are of the view that these factors are critical considerations for whether an individual is able to provide informed consent, and concluded that these are factors that a provider would be expected to assess when determining if the individual is capable of understanding the information provided in the notice and the implications of consenting. The HHS interim final rules therefore establish requirements related to the notice and consent exception. HHS considered a number of alternatives in developing these interim final rules. HHS considered different standards to apply in defining geographic regions for purposes of language access requirements. The HHS interim final rules require providers and facilities to provide the notice and consent documents in the 15 most common language in the state, or in a geographic region, which reasonably reflects the geographic region served by the applicable facility. HHS also considered the use of MSAs,¹⁷⁶ hospital service areas (HSAs),¹⁷⁷ hospital referral regions (HRRs),¹⁷⁸ and public use microdata areas (PUMAs),¹⁷⁹ applied based on where the applicable facility is located. These geographic regions might better reflect a facility's service area than a state. However, HHS is of the view that allowing providers and facilities to use the state as the geographic region would reduce burden, and concluded that the standard in the

HHS interim final rules provides sufficient flexibility for providers and facilities to determine how best to serve their population. HHS considered requiring that a provider or facility that uses a region other than a state must use a geographic region smaller than a state, but determined this approach would not adequately address the needs to facilities that serve populations that cross state borders. HHS also considered alternatives regarding the inapplicability of the notice and consent exception to ancillary services. HHS considered expanding the definition of ancillary services to include other services for which surprise billing frequently occurs. In particular, stakeholders raised concerns about providers who deliver services to individuals during inpatient stays, but who the individual has little involvement in selecting. These included, for example, providers furnishing mental health services, cardiology services, and rehabilitative services. The Departments are concerned about surprise bills that arise in these situations, but prefer to further consider the recommendation. Individuals may have strong preferences to select these types of providers for out-of-network care, and it is therefore not clear whether they would be appropriate to include among the types of specialties for which notice and consent to be balance billed is prohibited.

Applicability date. The Departments considered delaying the applicability date of these interim final rules in response to stakeholder feedback regarding the challenges of coming into compliance with these interim final rules by January 1, 2022. The Departments recognize the challenges that providers (including providers of air ambulance services), facilities, plans, and issuers will face in making the necessary changes to comply with these new requirements. However, delaying the applicability date would have significant ramifications for participants, beneficiaries, and enrollees and would continue to leave them vulnerable to surprise bills. Therefore, the Departments concluded that it is in the public interest to require these interim final rules to be applicable in accordance with the applicability dates in the No Surprises Act.

Provider Disclosure Requirements Regarding Patient Protections against Balance Billing. Section 2799B–3 of the PHS Act, as added by the No Surprises Act, requires providers and facilities to provide disclosures regarding patient protections against balance billing. These interim final rules include

provisions to limit this disclosure requirement to certain providers and facilities, and with respect to certain individuals. These interim final rules also include a special rule to limit unnecessary duplication, so that a facility's disclosure may satisfy the disclosure requirement on behalf of providers in certain circumstances. HHS considered applying the disclosure requirement more broadly. However, HHS determined that a broader application of the disclosure requirements would increase the administrative costs associated with the requirement, without commensurate benefits to individuals. Rather, HHS was concerned that requiring the disclosure be made by facilities and providers in circumstances where the protections against balance billing would not apply could create consumer confusion about their rights under the No Surprises Act. Additionally, HHS determined that requiring providers to provide a disclosure when furnishing services at a facility that was also required to provide a disclosure was unnecessary and could be overwhelming to consumers. If providers furnishing services at a facility were required to provide a disclosure as well, at the very least, the cost of printing and materials for the notices would have doubled, for an additional \$2.5 million in costs. If, in addition, providers had to develop the notices they provided, there would have been additional costs. If all providers were required to provide a notice, regardless of whether the services are furnished at a provider's office or a health care facility, then in addition to the 39,690,940 individuals treated in the emergency facilities,¹⁸⁰ 526,685,200 individuals visiting a provider's office or a health care facility would have been provided a disclosure, for a total of 566,376,140 disclosures.¹⁸¹ The cost to print the disclosures would have been approximately \$28.3 million, approximately \$25.8 million more than it is estimated to be under the provisions in these interim final rules.

¹⁸⁰ Agency for Healthcare Research and Quality, HCUP Fast Stats—Trends in Emergency Department Visits. <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide#export>.

¹⁸¹ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

¹⁷⁶ <https://www.census.gov/programs-surveys/metro-micro/about.html>.

¹⁷⁷ <https://www.dartmouthatlas.org/faq/>.

¹⁷⁸ <https://www.dartmouthatlas.org/faq/>.

¹⁷⁹ [https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20\(PUMAs\)%20are%20non%20Doverlapping%2C,and%20the%20U.S.%20Virgin%20Islands.](https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20(PUMAs)%20are%20non%20Doverlapping%2C,and%20the%20U.S.%20Virgin%20Islands.)

*D. Paperwork Reduction Act—
Department of Health and Human
Services*

Under the Paperwork Reduction Act of 1995 (PRA), HHS is required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that HHS 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 HHS' 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 is soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs).

1. Wage Estimates

To derive wage estimates, the Departments generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100

percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.¹⁸² Table 4 presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and the Departments are of the view that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 4—WAGE RATES

Occupation title	Occupational code	Mean hourly wage (\$/hour)	Fringe benefits and overhead (\$/hour)	Adjusted hourly wage (\$/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43–6014	\$19.43	\$19.43	\$38.86
Lawyer	23–1011	71.59	71.59	143.18
All Occupations	00–0000	27.07	27.07	54.14
Computer Programmers	15–1251	45.98	45.98	91.96
Medical Secretaries and Administrative Assistants	43–6013	18.75	18.75	37.50
Human Resources Specialists	13–1071	33.38	33.38	66.76
Business Operations Specialist	13–1198	38.57	38.57	77.14
General and Operations Manager	11–1021	59.15	59.15	118.30
Compensation and Benefits Manager	11–3111	65.94	65.94	131.88
Computer and Information Systems Managers	11–3021	77.76	77.76	155.52

2. ICRs Regarding Information To Be Shared About QPA (45 CFR 149.140(d))

These interim final rules require plans and issuers to provide certain information regarding the QPA to nonparticipating providers, or nonparticipating emergency facilities in cases in which the recognized amount with respect to an item or service furnished by the provider or facility is the QPA (and in all cases subject to these rules for nonparticipating providers of air ambulance services). Specifically, plans and issuers must provide the following information to providers (including air ambulance providers) and facilities, when making an initial payment or notice of denial of payment: (1) The QPA for each item or service involved; (2) a statement certifying that the plan or issuer has determined that the QPA applies for the purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and each QPA was determined in compliance with the methodology

established in these interim final rules; (3) a statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and (4) contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service. Additionally, upon request of the provider or facility, the plan or issuer must provide, in a timely manner, the following information: (1) Whether the QPA for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether

the QPA for those items and services was determined using underlying fee schedule rates or a derived amount; (2) if a related service code was used to determine the QPA for a new service code, information to identify the related service code; (3) if the plan or issuer used an eligible database to determine the QPA, information to identify which database was used; and (4) if applicable, upon request, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, or other incentive-based or retrospective payments or payment adjustments for covered items and services that were excluded for purposes of calculating the QPA.

The Departments assume that TPAs will provide this information on behalf of self-insured plans. In addition, the Departments assume that issuers and TPAs will automate the process of preparing and providing this information in a format similar to an explanation of benefits as part of the system to calculate the QPA. The cost to issuers and TPAs of making the changes

¹⁸² See May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National

Occupational Employment and Wage Estimates,

available at https://www.bls.gov/oes/current/oes_nat.htm.

to their IT systems is discussed previously in the RIA.

The Departments estimate that a total of 1,758 issuers and TPAs will incur burden to comply with this provision. Currently, 14 states have established some payment standards for services provided by nonparticipating providers or nonparticipating emergency facilities. Therefore, the Departments assume that issuers and TPAs will potentially need to calculate the QPA for two-thirds of the claims involving nonparticipating providers or nonparticipating emergency facilities.

In 2018, there were approximately 39,690,940 emergency department visits for patients with individual market or group health coverage.¹⁸³ The Departments estimate that approximately 18 percent of these visits¹⁸⁴ will include services provided by nonparticipating providers or nonparticipating emergency facilities and plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the specified information along with the initial payment or denial notice for approximately 4,786,727 claims annually from nonparticipating providers or nonparticipating emergency facilities for emergency department visits. In addition, in 2018, there were approximately 4,146,476 emergency department visits that resulted in hospital admission for patients with individual market or group health coverage. Using this as an estimate of post-stabilization services provided in emergency facilities, and assuming that in 16 percent of cases the patient is treated at a nonparticipating emergency facility or by a nonparticipating provider at a

participating facility,¹⁸⁵ the Departments estimate that approximately 663,436 individuals will have the potential to be treated by a nonparticipating provider or facility. In the absence of data, the Departments assume that in 50 percent of cases services will be provided by nonparticipating providers without satisfying the notice and consent criteria in these interim final rules for reasons such as unforeseen, urgent medical needs and lack of participating providers in the facility. The Departments estimate that plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the required information along with the initial payment or denial notice for approximately 222,251 claims from nonparticipating providers or nonparticipating emergency facilities for post-stabilization services. Additionally, based on 2016 data, the Departments estimate that there will be 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures for individuals with group health coverage or individual market coverage.¹⁸⁶ The Departments assume that in 16 percent of cases the patient will have the potential to receive care from a nonparticipating provider at a participating facility, and that in approximately 5 percent of those cases services will be provided by nonparticipating providers without satisfying the notice and consent criteria in these interim final rules for reasons such as the services being ancillary services or related to unforeseen, urgent medical needs, and plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the required information along with the initial payment or denial notice for approximately 59,534 claims annually for non-emergency services furnished by

a nonparticipating provider at a participating health care facility. In total, plans and issuers will be required to provide documents related to QPAs along with the initial payment or denial of payment for approximately 5,068,512 claims annually from nonparticipating providers or facilities.

The Departments estimate that for each issuer or TPA it will take a medical secretary 10 minutes (at an hourly rate of \$37.50) to prepare the documentation and attach it to each payment or denial notice or explanation of benefits sent to the nonparticipating provider or facility. The Departments assume that this information will be sent electronically at minimal cost. The total annual burden for all issuers and TPAs to provide the QPA information and certification along with 5,068,512 payments or denial notices, is estimated to be approximately 844,752 hours, with an associated equivalent cost of approximately \$31.7 million.

The Departments assume that for the 5,068,512 QPA information sent to nonparticipating providers or nonparticipating emergency facilities, 50 percent will result in requests to provide additional information and plans and issuers will be required to send additional information to approximately 2,534,256 providers or facilities. The Departments estimate that it will take a medical secretary 15 minutes (at an hourly rate of \$37.50) to prepare the document and provide it to the provider or facility that requested it. The Departments assume that this information will be delivered electronically with minimal additional cost. The total estimated burden, for all issuers and TPAs, will be approximately 633,564 hours annually, with an associated equivalent cost of approximately \$23.8 million.

The total annual burden for all issuers and TPAs for providing the initial and additional information related to QPA will be 1,478,316 hours, with an equivalent cost of \$55,436,853. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 739,158 burden hours with an equivalent cost of approximately \$27,718,427. The Departments seek comment on these burden estimates.

¹⁸³ Agency for Healthcare Research and Quality, HCUP Fast Stats—Trends in Emergency Department Visits. <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide>.

¹⁸⁴ Estimate from Pollitz, K. et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>.

¹⁸⁵ Estimate from Pollitz, K. et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>.

¹⁸⁶ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

TABLE 5—ANNUAL BURDEN AND COST FOR PLANS AND ISSUERS TO PROVIDE INFORMATION RELATED TO QPA TO NONPARTICIPATING PROVIDERS AND NONPARTICIPATING EMERGENCY FACILITIES

	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
Initial information	879	2,534,256	0.167	422,376	\$15,839,100.93
Additional Information	879	1,267,128	0.25	316,782	11,879,325.70
Total	879	3,801,384		739,158	27,718,427.63

3. ICRs Regarding Audits of QPA (45 CFR 149.140(f))

The No Surprises Act provides that rulemaking must establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved.

These interim final rules include an audit provision establishing that the Departments' existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA consistent with these interim final rules.

HHS has primary enforcement authority over issuers (in a state if the Secretary of HHS makes a determination that a state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act) and non-federal governmental plans, such as those sponsored by state and local government employers and expects to conduct no more than 9 audits annually. Therefore, this

collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

4. ICRs Regarding Disclosure for Self-Insured Plans Opting-In to State Law (45 CFR 149.30)

These interim final rules allow self-insured group health plans, including self-insured non-federal governmental plans, to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)–(d) of the Code, section 716(a)–(d) of ERISA, and section 2799A–1(a)–(d) of the PHS Act. A self-insured plan that has chosen to opt-in to a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

Based on available data, HHS estimates that approximately 84 self-insured non-federal governmental plans in New Jersey, Nevada, Virginia and

Washington¹⁸⁷ will opt-in and incur the one-time burden and cost to include the disclosure in their plan documents in 2022. It is estimated that for each plan an administrative assistant will spend 1 hour (at an hourly rate of \$38.86) and a compensation and benefits manager will spend 30 minutes (at an hourly rate of \$131.88) to prepare the disclosure. The estimated total burden for each plan will be 1.5 hours with an equivalent cost of approximately \$105. The estimated total annual burden for all 84 plans will be approximately 126 hours with an equivalent cost of approximately \$8,783. HHS estimates that there are approximately 11,956 policyholders in these plans that will be provided the disclosure. HHS assumes that only printing and material costs are associated with the disclosure requirement, because the notice can be incorporated into existing plan documents. HHS estimates that the disclosure will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of plan documents will be delivered electronically at minimal cost.¹⁸⁸ Therefore, the cost to deliver 66 percent of these disclosures in print is estimated to be approximately \$197. The total one-time cost for all plans, incurred in 2022, is estimated to be approximately \$8,981.

TABLE 6—ONE-TIME BURDEN AND COST TO PROVIDE DISCLOSURE REGARDING OPTING IN TO STATE LAW

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated printing and materials cost	Total estimated cost
2022	84	84	1.5	126	\$8,783	\$197	\$8,981

5. ICRs Regarding Complaints Process for Surprise Medical Bills (45 CFR 149.150, 45 CFR 149.450)

The No Surprises Act directs the Departments to establish a process to

receive complaints regarding violations of the application of the QPA requirements by group health plans and health insurance issuers offering group or individual health coverage under

section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and section 2799A–1(a)(2)(B)(iv) of the PHS Act, and violations by health care provider, facilities, and providers of air

¹⁸⁷ Based on data on self-insured plans that have opted in available at: <https://www.insurance.wa.gov/self-funded-group-health-plans>, <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health->

[insurance-bulletin-2019.pdf](https://www.insurance-bulletin-2019.pdf), <https://scc.virginia.gov/balancebilling>.

¹⁸⁸ According to data from the National Telecommunications and Information Agency, 34 percent of households in the United States accessed

health records or health insurance online. <https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show>.

ambulance services of the requirements under sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act. The Departments are of the view that the complaints process should extend to all of the balance billing requirements and define a complainant as any individual, or their authorized representative, who files a complaint, as described and defined in these interim final rules. This regulatory action is taken as required by the No Surprises Act, which directs the Departments to

create a process for balance billing complaints regarding plans and issuers, and directs HHS to create a process for balance billing complaints regarding providers and facilities. HHS estimates that there will be, on average, 3,600 balance billing complaints against providers, facilities, providers of air ambulance services, plans, and issuers submitted annually. HHS estimates that it will take each complainant 30 minutes (at an hourly rate of \$54.14)¹⁸⁹ to collect all relevant

documentation related to the alleged violation and to access and complete the provided complaint form, with an equivalent cost of approximately \$27. The total burden for all complainants is estimated to be 1,800 hours, with an equivalent annual cost of approximately \$97,452. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, approximately 900 burden hours with an equivalent cost of approximately \$48,726.

TABLE 7—ANNUAL BURDEN AND COSTS FOR COMPLAINTS RELATED TO SURPRISE BILLING

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Cost per response	Total annual burden (hours)	Total estimated cost
1,800	1,800	0.5	\$27.07	900	\$48,726

6. ICRs Regarding Notice of Right To Designate a Primary Care Provider (45 CFR 149.310(a)(4))

These interim final rules continue to require that if a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or coverage and their right to designate a primary care provider. For group health plans and group health insurance coverage, the notice must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or coverage. For individual health insurance coverage, the notice must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance. These interim final rules continue to include model language to satisfy the notice requirements. The No Surprises Act extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. The patient protections under section 2719A of the PHS Act apply to only non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. In contrast, the patient protections under the No Surprises Act apply generally to all group health plans and group and

individual health insurance coverage, including grandfathered health plans. Therefore, the requirements regarding patient protections for choice of health care professional under these interim final rules will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022.

In order to satisfy the patient protection disclosure requirement, state and local government plans and issuers in the individual market will need to notify policy holders of their plans’ policy in regards to designating a primary care physician and for obstetrical or gynecological visits and will incur a one-time burden and cost to incorporate the notice into plan documents. Non-federal governmental plans and individual market plans that are currently not grandfathered have already incurred the one-time cost to prepare and incorporate this notice in their existing plan documents.

There are an estimated 90,126 non-federal governmental employers offering health plans to employees and 388 health insurance issuers in the individual market. HHS estimates that there are approximately 14,417 grandfathered non-federal government employer-sponsored plans and approximately 837,543 grandfathered individual market policies, with approximately 6,055 grandfathered non-federal governmental plans offering HMO and point-of-service (POS) options.¹⁹⁰ HHS assumes that all individual market issuers offer at least

one HMO, exclusive provider organization (EPO) or POS options. It is estimated that in 2022, 5,450 grandfathered non-federal governmental plans and individual market policies will be subject to this notice requirement. While not all HMO, EPO, and POS options require the designation of a primary care physician or a prior authorization or referral before an OB/GYN visit, HHS is unable to estimate this number. Therefore, this estimate should be considered an overestimate of the number of affected entities.

These interim final rules continue to provide model language for the notice. It is estimated that each plan or issuer will require a compensation and benefits manager (at an hourly rate of \$131.88) to spend 10 minutes customizing the model notice to fit the plan’s specifications. Each plan or issuer will also require clerical staff (at an hourly rate of \$38.86) to spend 5 minutes adding the notice to the plan’s documents. The estimated total burden for each plan or issuer will be 0.25 hours with an equivalent cost of approximately \$25. In 2022, the estimated total annual burden for all 5,450 plans and issuers will be approximately 1,362 hours with an equivalent cost of approximately \$137,430. There will be no additional burden and cost in 2023 to prepare the notice, since all plans and issuers will have incurred the burden and cost by 2022.

HHS estimates that there are approximately 1.8 million non-federal governmental plan policyholders in grandfathered plans, with an estimated

¹⁸⁹ The Departments use the average wage rate for all occupations.

¹⁹⁰ According to 2020 Kaiser/HRET survey of Employer Health Benefits, 11 percent of employers offer a health maintenance organization (HMO) option and that 31 percent of employers offer a

point-of-service (POS) option. Available at <https://www.kff.org/health-costs/report/2020-employer-health-benefits-survey/>.

413,976 policyholders enrolled in grandfathered HMO and POS plans options.¹⁹¹ In addition, there are an estimated 837,543 policyholders with grandfathered individual market plans. It is estimated that approximately 75 percent of individual market enrollees are enrolled in HMO, EPO, and POS options.¹⁹² Therefore, an estimated 627,146 policyholders in the individual market have grandfathered plans with

HMO, EPO, and POS options. It is estimated that approximately 937,010 policyholders will remain in grandfathered non-federal government employer sponsored and individual market plans with HMO, EPO, and POS options in 2022 and will receive the required notice for the first time in 2022. HHS assumes that only printing and material costs are associated with the disclosure requirement, because the

notice can be incorporated into existing plan documents. HHS estimates that the notice will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of the notices will be delivered electronically at minimal cost.¹⁹³ Therefore, the cost to deliver 66 percent of these notices in print is estimated to be approximately \$15,461.¹⁹⁴

TABLE 8—ONE-TIME BURDEN AND COST TO PROVIDE NOTICE OF RIGHT TO DESIGNATE A PRIMARY CARE PROVIDER

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated printing and materials cost	Total estimated cost
2022	5,450	5,450	0.25	1,362	\$137,430	\$15,461	\$152,891

HHS will revise the burden currently approved under OMB Control Number 0938–1094, (Notice of Rescission of Coverage and Disclosure Requirements for Patient Protection under the Affordable Care Act, CMS–10330, expiration: July 31, 2022) to account for this burden.

7. ICRs Regarding Notice and Consent To Waive Balance Billing Protections, Retention of Certain Documents, and Notice to Plan or Issuer (45 CFR 149.410(b)–(e), 45 CFR 149.420(c)–(i))

The No Surprises Act and these interim final rules require that a plan or issuer providing coverage of emergency services do so without the individual or the health care provider having to obtain prior authorization and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services (regardless of the department of the hospital in which such items and services are furnished). Emergency services include any additional items and services that are covered under a plan or coverage after a participant, beneficiary, or enrollee is stabilized (referred to as post-stabilization services) unless certain notice and consent requirements are met. The No Surprises Act and these interim final rules further apply surprise billing protections in the case of non-emergency services furnished by nonparticipating providers during a visit by a participant, beneficiary, or

enrollee at participating health care facilities unless notice and consent as specified in these interim final rules have been met. The requirements related to the notice and consent, applicable exceptions, and timing are set forth in section 2799B–2 of the PHS Act, and implemented at 45 CFR 149.410 and 45 CFR 149.420 of these interim final rules.

In order to meet the notice and consent requirements of these interim final rules, nonparticipating providers and nonparticipating emergency facilities must provide the participant, beneficiary, or enrollee with a notice, meet certain timing requirements, and obtain consent from the participant, beneficiary, or enrollee as described in 45 CFR 149.420 and these interim final rules. The provided notice must: (1) State the health care provider or facility is a nonparticipating provider or facility; (2) include the good faith estimate of what the individual may be charged, including any item or service that is reasonably expected to be provided in conjunction with such items and services; (3) provide information about whether prior authorization or other care management limitations may be required; and (4) clearly state that consent to receive such items or services is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, in which case the individual's cost-sharing responsibility would be at the in-network level. In cases where post-

stabilization services are furnished by a nonparticipating provider at a participating emergency facility, the notice must also include a list of participating providers at the participating emergency facility who are able to furnish the items or services involved and inform the individual that they may be referred, at their option, to such a participating provider.

Additionally, a nonparticipating provider or nonparticipating emergency facility must provide the participant, beneficiary, or enrollee, or such individual's authorized representative, with the notice and consent documents in any of the 15 most common languages in the state, or a geographic region that reasonably reflects the geographic region served by the applicable facility. If the individual's preferred language is not among the 15 most common languages made available or the individual cannot understand the language in which the notice and consent document are provided the individual must be provided with a qualified interpreter.

In addition to providing the required notice and consent, nonparticipating emergency facilities, participating health care facilities, and nonparticipating providers are obligated to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished. Where the notice and consent requirements described in this interim final rule have been met, the

¹⁹¹ According to the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits, 12 percent of covered workers in non-federal government plans have an HMO option and that 11 percent of covered workers have a POS option.

¹⁹² Estimate based of data reported in Unified Review Template Submissions for 2018 plan. Rate

review data available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/ratereview.html>.

¹⁹³ According to data from the National Telecommunications and Information Agency, 34 percent of households in the United States accessed health records or health insurance online. [https://www.ntia.doc.gov/blog/2020/more-half-american-](https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show)

[households-used-internet-health-related-activities-2019-ntia-data-show](https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show).

¹⁹⁴ 937,010 notices × 66% = 618,427 notices printed × \$0.05 per page × 1/2 pages per notice = approximately \$15,461.

nonparticipating provider, the participating health care facility on behalf of the nonparticipating provider, or the nonparticipating emergency facility, as applicable, must timely notify the plan or issuer, respectively, that the notice and consent criteria have been met, and if applicable, provide to the plan or issuer a copy of the signed notice and consent documents. In instances where, to the extent permitted by these rules, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice and consent documents with the bill to the participant, beneficiary, or enrollee. In addition, for items and services furnished by a nonparticipating provider at a participating health care facility, the provider (or the participating facility on behalf of the provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility.

In order to meet the notice and consent requirements of the statute and these interim final rules, nonparticipating providers and nonparticipating emergency facilities must provide the participant, beneficiary, or enrollee with a notice. HHS is specifying in guidance mandatory notice and consent forms that will require customization by the provider or facility.

HHS assumes that emergency facilities and health care facilities will provide the notice and obtain consent on behalf of nonparticipating providers, retain records and notify plans and issuers. HHS estimates that a total of 17,467 health care facilities and emergency departments (including 475 hospital-affiliated satellite and 270 independent freestanding emergency departments) will be subject to these requirements. HHS assumes that for hospital-affiliated satellite freestanding emergency departments, the notice and consent will be developed by the parent hospital. Therefore, the burden to develop the notice and consent documents will be incurred by 16,992 emergency facilities and health care facilities. HHS estimates that for each facility it will take a lawyer 1 hour (at an hourly rate of \$143.18) to read and understand the notice and consent forms and make any required and applicable alteration, an administrative assistant half an hour (at an hourly rate of \$38.86) to make any alterations to the provided notice and consent documents and prepare the final documentation, a computer programmer 1 hour (at an hourly rate of \$91.96) to digitize and

post on a shared network server or push to networked computers fillable versions of the notice and consent documents, and a Computer and Information Systems Manager half an hour (at an hourly rate of \$155.52) to verify accessibility to, and ensure functionality of, the notice and consent documents. HHS also estimates each facility will incur an additional cost of approximately \$1,000 (at \$500 per document) to contract with an outside firm to translate the notice and consent documents into the 15 most common languages in the state or a geographic region that reasonably reflects the geographic region served by the applicable facility. HHS estimates the one-time first-year burden, to be incurred in 2021, to make alterations, prepare the final versions, translate and make accessible to the providers within the facility the notice and consent documentation, for each facility will be approximately 3 hours, with an associated equivalent cost of approximately \$1,332. For all 16,992 emergency facilities and health care facilities, HHS estimates a total one-time first-year burden of 50,976 hours, with an associated equivalent cost of approximately \$22.6 million.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to post-stabilization services, when emergency services are provided by nonparticipating providers or nonparticipating emergency facilities, the provider or facility must provide the participant, beneficiary, or enrollee with a notice and obtain consent to be treated by the nonparticipating emergency facility or nonparticipating provider. HHS estimates there are approximately 5,533 emergency departments (including hospital-affiliated satellite and independent freestanding emergency departments)¹⁹⁵ that could be subject to the notice and consent requirements in these interim final rules and will incur ongoing annual costs and burdens, beginning in 2022. In 2018, there were approximately 4,146,476 emergency department visits that resulted in hospital admission for patients with individual market or group health coverage.¹⁹⁶ Using this as an estimate of post-stabilization services

provided in emergency facilities, and assuming that in 16 percent of cases the patient is treated at a nonparticipating emergency facility or by a nonparticipating provider at a participating facility, HHS estimates that approximately 663,436 individuals will be provided with a notice and consent document for post-stabilization services. HHS anticipates that the notice and consent will be used infrequently for post-stabilization services, so this estimate is an upper bound. HHS estimates it will take a medical secretary 2 hours (at an hourly rate of \$37.50) to customize the required notice and consent documents, generate a list of participating providers, provide and explain the documents to the individual (or authorized representative), answer questions, and obtain the signed consent if the individual agrees, provide the signed documents on paper or, as practicable, electronically, as selected by the individual, and retain the documentation as required by these interim final rules. The total burden for providing the notice and consent documents to individuals at all emergency facilities will be 1,326,872 hours with an equivalent cost of approximately \$49.8 million. HHS assumes that these documents will be provided directly to each affected individual (or authorized representative) in paper format and will be 4 pages (2 pages printed double-sided) on average. Assuming a cost of \$0.10 (at \$0.05 per page for printing and material cost) for each notice and consent document, the total printing and material costs for all notices will be approximately \$66,344. The total ongoing cost for all emergency facilities will be approximately \$49.8 million annually. HHS assumes that nonparticipating providers and nonparticipating emergency facilities will notify the plan or issuer and provide a copy of the signed notice and consent documents along with the claim form electronically at minimal cost.

HHS estimates that each individual that receives notice and consent from an emergency facility will require, on average, 45 minutes (at an hourly rate of \$54.14) to read and understand and sign the required notice and consent documents, with a total cost of approximately \$41. For all 663,436 individuals that could potentially receive the notice and consent documents, HHS estimates a total annual burden of 497,577 hours, with an associated total annual cost of approximately \$26.9 million.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to non-emergency services

¹⁹⁵ Emergency Medicine Network, 2018 National Emergency Department Inventory—USA. Available at <https://www.emnet-usa.org/research/studies/medi/medi2018/>.

¹⁹⁶ Agency for Healthcare Research and Quality, HCUP Fast Stats—Trends in Emergency Department Visits. Available at <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTableState=hide&definitionsState=hide&exportState=hide>.

furnished by a nonparticipating provider at a participating health care facility, if an individual schedules an appointment for such items or services at least 72 hours before the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, no later than 72 hours before the date of the appointment. If an individual schedules an appointment for such items or services within 72 hours of the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, on the day that the appointment is made. In the situation where an individual is provided the notice on the same day that the items or services are furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements applies.

HHS estimates there are approximately 16,722 health care facilities that will be subject to the notice requirement described in these interim final rules and will incur ongoing annual costs and burdens beginning in 2022. Based on 2016 data, HHS estimates that there will be 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures for individuals with group

health coverage or individual market coverage¹⁹⁷ and that approximately 16 percent of those visits will involve a nonparticipating provider.¹⁹⁸ This estimate is a lower bound since it is based on the number of postoperative office visits and potentially excludes situations where such visits were not needed or such follow-up was conducted at a different setting. HHS therefore estimates that approximately 1,777,129 individuals could potentially face balance billing and will be subject to the notice requirements of these interim final rules. With respect to non-emergency services furnished by a nonparticipating provider at a participating health care facility, HHS estimates it will take a medical secretary 1 hour (at an hourly rate of \$37.50) to customize the required notice, generate a list of participating providers, provide the document via email or mail, as selected by the individual, and answer any questions. For all health care facilities, HHS estimates a total annual ongoing annual burden of approximately 1,777,129 hours, with an associated annual cost of approximately \$66.6 million. HHS estimates that approximately 66 percent of the notices will be mailed to individuals (34 percent sent electronically) at a cost of \$0.65 (at \$0.05 per page for printing and material cost and \$0.55 postage).¹⁹⁹ Assuming minimal cost for electronic

delivery, the total cost of printing and mailing the notice and consent documents will be approximately \$762,388 annually. The total ongoing cost for all health care facilities will be approximately \$67.4 million annually.

HHS estimates that each individual that receives the notice will require, on average, 45 minutes (at an hourly rate of \$54.14) to read and understand the required notice, with a total cost of \$41. For all 1,777,129 individuals that could receive the notice document, HHS estimates a total annual burden of 1,332,847 hours, with an associated total annual cost of \$72.2 million. HHS assumes that nonparticipating providers (or the participating facilities on behalf of the providers) will notify the plan or issuer and provide a copy of the signed notice and consent documents along with the claim from the participating facility electronically at minimal cost.

For all emergency and health care facilities, the total ongoing burden will be 3,104,001 hours annually and the total cost, including printing and materials cost, will be approximately \$117,228,780 annually starting in 2022. For all consumers, the total annual burden to read and understand the notice will be 1,830,424 hours with an equivalent cost of \$99,099,147 starting in 2022.

TABLE 9—ONE-TIME AND ANNUAL BURDEN AND COST FOR EMERGENCY DEPARTMENTS AND FACILITIES RELATED TO NOTICE AND CONSENT

Year	Estimated number of respondents	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Total estimated translating, printing and materials cost	Total estimated cost
2021	16,992	16,992	50,976	\$5,646,951	\$16,992,000	\$22,638,951
2022	17,467	2,440,565	3,104,001	116,400,048	828,732	117,228,780
2023	17,467	2,440,565	3,104,001	116,400,048	828,732	117,228,780
3 Year Average	17,309	1,632,707	2,086,326	79,482,349	183,634	85,698,837

TABLE 10—ANNUAL BURDEN AND COST FOR INDIVIDUALS RELATED TO NOTICE AND CONSENT STARTING IN 2022

Estimated number of respondents	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2,440,565	2,440,565	1,830,424	\$99,099,147	\$99,099,147

¹⁹⁷ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

¹⁹⁸ Estimated based on information provided by KFF. Available at: <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>.

¹⁹⁹ According to data from the National Telecommunications and Information Agency, 34

percent of households in the United States accessed health records or health insurance online. <https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show>.

8. ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)

Section 2799B–3 of the PHS Act, as added by the No Surprises Act and codified at 45 CFR 149.430, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Specifically, health care providers and facilities (including an emergency department of a hospital or independent freestanding emergency department) are required to make publicly available, post on a public website of the provider or facility, and provide to participants, beneficiaries, and enrollees a one-page notice about surprise billing protections, which must include information about any applicable state requirements, and about how to contact appropriate state and federal agencies if the individual believes the provider or facility has violated the balance billing rules. The required notice must include clear and understandable language that explains the requirements and prohibitions relating to the prohibitions on balance billing in cases of emergency services and in cases of non-emergency services performed by a nonparticipating provider at certain participating facilities, explain any other applicable state laws, and provide contact information for the appropriate state and federal agencies that an individual may contact if they believe the provider or facility has violated a requirement described in the notice.

Health care providers and facilities are required to publicly post and make the disclosure publicly available through a public website accessible free of charge that is easily accessible, without barriers, including via search engines, and that ensures that the information is accessible to the general public. HHS assumes that providers and facilities will enter into agreements for the facilities to provide the disclosure on behalf of the providers and that the required language and information will be developed, posted within the facility, and posted on a public website by the facility. This will ameliorate the burden and cost for the individual provider. Many facilities and providers will be able to enter into an agreement at minimal cost if they renew their contracts prior to 2022. For each facility whose contracts with providers are not due to be renewed before 2022, the burden to enter into agreements related to this disclosure will vary based on the number of providers that practice within the facility. HHS estimates that for each facility, on average, it will take a lawyer 2 hours (at an hourly rate of

\$143.18) to draft an agreement and an administrative assistant 2 hours (at an hourly rate of \$38.86) to provide electronic copies to all providers to sign. The total burden for all 17,467 facilities will be 69,868 hours with an equivalent cost of approximately \$6,359,385, to be incurred as one-time costs in 2021. HHS is unable to estimate how many providers will incur burden to sign the agreement, but anticipates that the burden to sign each agreement will be minimal. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

HHS estimates a total of 17,467 health care facilities (including 475 hospital-affiliated satellite and 270 independent freestanding emergency departments) will incur burden and costs to comply with this provision. HHS assumes that for hospital-affiliated satellite freestanding emergency departments, the disclosure will be developed by the parent hospital. HHS estimates that for each facility, on average, it will take a lawyer 2 hours (at an hourly rate of \$143.18) to read and understand the provided notice and draft any additional, clear, and understandable language as may be needed, an administrative assistant 30 minutes (at an hourly rate of \$38.86) to prepare the final document for distribution and make the information publicly available within the facility, and a computer programmer 1 hour (at an hourly rate of \$91.96) to post the information on a separate or existing web page, in a searchable manner, and to make the content available in an easily downloadable format. The burden will be higher for facilities in states with state laws or All-Payer Model Agreements, but lower for facilities in states without any state laws. HHS assumes that each facility will post a single page document in at least two prominent locations, such as where individuals schedule care, check-in for appointments, or pay bills, and estimates that each facility will incur a printing cost of \$0.10 (at \$0.05 per page for printing and materials) in order to post the required disclosure information prominently at each health care facility. HHS anticipates that hospitals will post 6 notices on average, and incur an additional cost of \$0.20 each. In addition, HHS assumes that each of the 475 hospital-affiliated satellite freestanding emergency departments will post two notices on average and incur a cost of \$0.10 each. HHS estimates the one-time burden, to be incurred in 2021, to develop, prepare, and post the required disclosure

information, for each facility will be approximately 3.5 hours, with an associated equivalent cost of approximately \$398. For all facilities, HHS estimates a total one-time burden of 59,472 hours, with an associated cost of approximately \$6.8 million, including materials and printing costs. HHS recognizes that there are some small providers and facilities that do not maintain or provide a publicly available website. Such entities are not required to make a disclosure on a public website. Therefore, HHS considers the estimate to be a high-end estimate.

HHS encourages states to develop language to assist providers and facilities in fulfilling this disclosure requirement. There are currently 33 states that have enacted laws to provide some protection to consumers for surprise billing. Some or all of these states may choose to develop model language. HHS assumes that it will take a lawyer 2 hours (at an hourly rate of \$143.18) and an administrative assistant 1 hour (at an hourly rate of \$38.86) to develop and amend the model language. The total one-time burden, to be incurred in 2021, for each state will be 3 hours with an equivalent cost of approximately \$325. For all 33 states, HHS estimates the total one-time burden will be 99 hours with an equivalent cost of approximately \$10,732.

In addition to requiring providers and facilities to publicly post and make the required disclosure publicly available through a public website, providers and facilities are required to provide individuals the required disclosure information in a one-page notice. The required notice must be provided in-person, through the mail or via email, as selected by the participant, beneficiary, or enrollee no later than the date on which the health care provider or health care facility requests payment from the individual (including requests for copayment made at the time of a visit to the provider or facility), or with respect to individual from whom the health care facility or health care provider does not request payment, no later than the date on which the health care provider or health care facility submits a claim to the group health plan or health insurance issuer. HHS assumes that, in order to reduce burden and costs, facilities will choose to provide the required disclosure to the individual (or their selected representative) at the time the individual is processed for any visit, upon check-in, or when other standard disclosures are shared with individuals with minimal additional burden. HHS estimates that there will be approximately 39,690,940 emergency

department visits²⁰⁰ and 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures²⁰¹ for individuals with group health coverage or individual market coverage. This is a lower bound for the number of patients who will receive the disclosure since HHS lacks comprehensive data on patients who receive services on all health care facilities. In order to provide the required disclosure to individuals each facility will incur a cost of approximately \$0.05 for printing and materials for each disclosure. HHS assumes that this disclosure will be

provided along with other forms and notices usually provided to individuals without incurring significant labor cost. For all facilities, HHS estimates a total annual ongoing annual cost of \$2.5 million, starting in 2022. HHS recognizes that the number of notices provided by each facility will vary depending on the number of annual visits and that some facilities could incur higher costs to provide the disclosure while others could incur lower costs. HHS assumes that all disclosures will be provided in-person; however, HHS acknowledges that some individuals will choose to have this

notice provided to them via email, at a minimal cost to the facility, and others may choose to receive the disclosure via mail, in which case the facility will incur additional postage costs.

HHS seeks comment on these burden estimates. Specifically, HHS seeks comment on the costs and burdens associated with posting the required information on a public website. HHS also seeks comment on the number of facilities that will be affected by these requirements and the number of individuals that would be required to receive the required notice.

TABLE 11—ONE-TIME BURDEN AND COSTS RELATED TO AGREEMENTS BETWEEN FACILITIES AND PROVIDERS

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Cost per response	Total annual burden (hours)	Total estimated cost
2021	17,467	17,467	4	\$364.08	69,868	\$6,359,385

TABLE 12—ONE-TIME AND ANNUAL BURDEN AND COST FOR FACILITIES TO PROVIDE DISCLOSURE ON PATIENT PROTECTIONS AGAINST BALANCE BILLING

Year	Estimated number of respondents	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Total estimated printing and materials cost	Total estimated cost
2021	17,467	17,467	59,472	\$6,758,568	\$2,965	\$6,761,533
2022	17,467	50,797,996	0	0	2,539,900	2,539,900
2023	17,467	50,797,996	0	0	2,539,900	2,539,900
3 Year Average	17,467	33,871,153	19,824	2,252,856	1,694,255	3,947,111

TABLE 13—ONE-TIME BURDEN AND COST FOR STATES TO DEVELOP STATE SPECIFIC LANGUAGE FOR FACILITIES TO PROVIDE DISCLOSURE ON PATIENT PROTECTIONS AGAINST BALANCE BILLING

Year	Estimated number of respondents	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost
2021	33	33	99	\$10,732.26

9. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act require plans and issuers to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act apply, information in plain language on

the provisions in these sections, and sections 2799B–1 and 2799B–2 of the PHS Act, and other applicable state laws on out-of-network balance billing, and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

The Departments assume that plans and issuers will use the model notice developed by HHS, and that TPAs will develop the notice for self-insured plans. The Departments estimate that on average for each plan or issuer it will

take a lawyer 2 hours (at an hourly rate of \$143.18) to read and understand the provided notice and draft any additional, clear, and understandable language as may be needed, an administrative assistant 30 minutes (at an hourly rate of \$38.86) to prepare the final document for distribution and make the information publicly available within the facility, and a computer programmer 1 hour (at an hourly rate of \$91.96) to post the information on a separate or existing web page, in a searchable manner, and to make the content available in an easily

²⁰⁰ Agency for Healthcare Research and Quality, HCUP Fast Stats—Trends in Emergency Department Visits.

²⁰¹ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

²⁰¹ Estimated based on information provided by KFF. Available at: <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>.

downloadable format. The total burden for an individual plan or issuer will be 3.5 hours with an equivalent cost of approximately \$398. The burden will be higher for issuers and TPAs in states with applicable state laws or All-Payer Model Agreements, but lower for issuers and TPAs in states without any applicable state laws. The Departments estimate that there are 1,553 issuers and 205 TPAs. The total burden for all issuers and TPAs will be 6,153 hours with an equivalent cost of \$699,245, to be incurred as a one-time cost in 2021. As DOL, the Treasury Department, and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 3,077 hours with an equivalent cost of approximately \$349,622.

The Departments assume that plans and issuers will also include the disclosure along with the explanation of

benefits at no additional cost. Under the same assumptions used to estimate the number of disclosures provided by nonparticipating facilities and nonparticipating providers, the Departments estimate that issuers and TPAs will include the disclosure to approximately 39,690,940 individuals who receive services at emergency facilities and 11,107,056 individuals who received non-emergency services at health care facilities, for a total of 50,797,996 disclosures. The Departments assume that 66 percent of these notices will be provided by mail and the cost of printing is \$0.05 per page.²⁰² Therefore, the total printing and materials cost for sending 33,526,677 notices by mail will be \$1,676,334 annually, starting in 2022. The Departments assume that for the disclosures sent by mail, it will take an administrative assistant 1 minute (at an

hourly rate of \$38.86) to print and enclose the notice with the explanation of benefits. The disclosures sent electronically can be sent at minimal cost. The total burden for all issuers and TPAs is estimated to be 558,778 hours with an equivalent cost of \$21,714,111. There will be no additional mailing costs, since the disclosure will be enclosed with the explanation of benefits. The total annual cost to all issuers and TPAs for sending the notices is estimated to be approximately \$23,390,445 starting in 2022. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 279,389 hours, with an equivalent cost of \$10,857,056, and printing and materials cost of \$838,167, for a total annual cost of \$11,695,223 starting in 2022.

TABLE 14—ONE-TIME AND ANNUAL BURDEN AND COST FOR PLANS AND ISSUERS TO PROVIDE DISCLOSURE ON PATIENT PROTECTIONS AGAINST BALANCE BILLING

Year	Estimated number of respondents	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Total estimated printing and materials cost	Total estimated cost
2021	879	879	3,077	\$349,622	0	\$349,622
2022	879	25,398,998	279,389	10,857,056	838,167	11,695,223
2023	879	25,398,998	279,389	10,857,056	838,167	11,695,223
3 year Average	879	16,932,958	187,285	7,354,578	558,778	7,913,356

10. Summary of Annual Burden Estimates for Information Collection Requirements

TABLE 15—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting	Total labor cost of reporting	Printing and materials cost	Total cost
45 CFR 149.140(d)	0938—NEW ...	879	3,801,384	0.19	739,158	\$37.50	\$27,718,427	0	\$27,718,427
45 CFR 149.30	0938—NEW ...	84	84	1.50	126	69.87	8,783	197	8,981
45 CFR 149.150, 149.450.	0938—NEW ...	1,800	1,800	0.5	900	54.14	48,726	0	48,726
45 CFR 149.310(a)(4)	0938—1094 ...	5,450	5,450	0.25	1362	100.87	137,430	15,461	152,891
45 CFR 149.410(b)—(e), 149.420(c)—(i)—Facilities and Providers.	0938—NEW ...	17,309	1,632,707	1.28	2,086,326	38.10	79,482,349	6,216,488	85,698,837
45 CFR 149.410(b)—(e), 149.420(c)—(i)—Consumers.	0938—NEW ...	2,440,565	2,440,565	0.75	1,830,424	54.14	99,099,147	0	99,099,147
45 CFR 149.430—Facilities and Providers.	0938—NEW ...	17,467	33,871,153	* 3.5	19,824	* 113.67	2,252,856	1,694,255	3,947,111
45 CFR 149.430—Facility and Provider agreements.	0938—NEW ...	17,467	17,467	4	69,868	91.02	6,359,385	0	6,359,385
45 CFR 149.430—States Section 2799A–5(c) of the PHS Act.	0938—NEW ...	33	33	3	99	108.41	10,732	0	10,732
	0938—NEW ...	879	16,932,958	0.01	187,285	39.27	7,354,578	558,778	7,913,356
Total		2,501,933	58,703,602		4,935,372		222,472,414	8,485,179	230,957,592

* Estimate based on burden incurred in first year only.

²⁰² According to data from the National Telecommunications and Information Agency, 34 percent of households in the United States accessed

health records or health insurance online. [https://www.ntia.doc.gov/blog/2020/more-half-american-](https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show)

[households-used-internet-health-related-activities-2019-ntia-data-show.](https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show)

11. Submission of PRA-Related Comments

HHS has submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule (CMS-9909-IFC), please visit the CMS website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410-786-1326.

E. Paperwork Reduction Act—Department of Labor and Department of the Treasury

As part of the continuing effort to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. This helps to ensure that the public understands the Departments' collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents.

Under the PRA, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number.

The information collections are summarized as follows:

1. ICRs Regarding Notice of Right To Designate a Primary Care Provider (26 CFR 54.9822-1T, 29 CFR 2590.722)

These interim final rules require that if a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or coverage and their right to designate a primary care provider. For group health plans and group health insurance coverage, the notice must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or coverage. For individual health

insurance coverage, the notice must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance. These interim final rules include model language to satisfy the notice requirements. The No Surprises Act extends the applicability of the patient protections for choice of health care professionals. The patient protections under section 2719A of the PHS Act apply to only non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. In contrast, the patient protections under the No Surprises Act apply generally to all group health plans and group and individual health insurance coverage, including grandfathered health plans. Therefore, the requirements regarding patient protections for choice of health care professional under these interim final rules will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022.

DOL estimates that there are 2.5 million ERISA-covered plans. Data obtained from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 16 percent of firms offering health benefits offer at least one grandfathered health plan. DOL estimates that five percent of plans will relinquish their grandfathered status in 2021. The data from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits also finds that 11 percent of plans have an HMO option and that 31 percent of plans offer a POS option. Thus, DOL estimates that in 2022, 161,148 grandfathered plans will be subject to this notice requirement.²⁰³

While not all HMO and POS options require the designation of a primary care physician or a prior authorization or referral before an OB/GYN visit, DOL is unable to estimate this number. Therefore, these estimates should be considered an overestimate of the number of affected entities.

Each of the plans will require a compensation and benefits manager to spend 10 minutes individualizing the model notice to fit the plan's specifications at an hourly rate of \$134.21.²⁰⁴ In 2022, this results in

²⁰³ 2.5 million ERISA-covered plans × 16% grandfathered plans × (100% minus 5% newly non-grandfathered plans) × (11% HMOs + 31% POSs) = 161,148 affected plans.

²⁰⁴ For more information on how the Department estimates labor costs see: <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.

26,858 hours of burden at an equivalent cost of \$3,604,602.

Each plan will also require clerical staff to spend 5 minutes adding the notice to the plan's documents at an hourly rate of \$55.14. In 2022, this results in 13,429 hours of burden at an equivalent cost of \$740,473.

Thus, the total hour burden associated with this ICR is 40,287 hours at an equivalent cost of \$4,345,075. DOL shares this burden equally with the Department of the Treasury. Therefore, the total hour burden for DOL and the Treasury Department is each approximately 20,143 hours at an equivalent cost of \$2,172,537.

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 58.2 percent of the notices will be delivered electronically.²⁰⁵

DOL estimates that there are 62.6 million ERISA-covered policyholders. Data obtained from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 14 percent of covered workers are enrolled in a grandfathered plan. DOL estimates that 5 percent of plans would relinquish their grandfathered status annually in 2021. The data from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits also finds that 13 percent of covered workers have an HMO option and that 8 percent of covered workers have a POS option. DOL estimates that plans will produce

²⁰⁵ According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

730,346 notices in 2022.²⁰⁶ This results in a cost burden of approximately \$18,259 in 2022.²⁰⁷ DOL shares this burden equally with the Department of the Treasury. Therefore, the total cost burden for DOL is approximately \$9,129 and the total cost burden for the Treasury Department is \$9,129. The summary of burden for this information collection has also been provided below.

Summary of Burden

Type of Review: Revised Collection.

Agency: DOL–EBSA, Treasury–IRS.

Title: Affordable Care Act Patient Protection Notice.

OMB Numbers: 1210–0142, 1545–2181.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Total Respondents: 161,148.

Total Responses: 730,346.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 40,287 (DOL—20,143;

Treasury—20,143).

Estimated Total Annual Burden Cost: \$18,259 (DOL—\$9,129; Treasury—\$9,129).

2. ICRs Regarding Information To Be Shared About QPA (26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d))

These interim final rules require plans and issuers to provide certain information to nonparticipating providers or nonparticipating emergency facilities in cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility is the QPA. Specifically, plans and issuers must provide the following information to providers (including air ambulance providers) and facilities, when making an initial payment or notice of denial of payment: (i) The QPA for each item or service involved; and (ii) a statement certifying that the plan or issuer has determined that the QPA applies for the purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and that each QPA was determined in compliance with 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6, or 45 CFR 149.140, as applicable. Additionally, upon request of the provider or facility, the plan or issuer must provide in a timely

manner the following information: (i) Whether the QPA for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount; (ii) if applicable, information to identify which database was used to determine the QPA; and (iii) if applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, or incentive based payments for covered items and services (as applicable) that were excluded for purposes of calculating the QPA.

As discussed earlier in HHS' PRA section, the total annual burden for all issuers and TPAs for providing the initial and additional information related to QPA will be 1,478,316 hours, with an equivalent cost of \$55,436,853. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. Thus, HHS will account for approximately 739,158 burden hours with an equivalent cost of approximately \$27,718,427. DOL and the Treasury Department will each account for 369,579 burden hours with an equivalent cost of approximately \$13,859,214.

3. ICRs Regarding Complaints Process for Surprise Medical Bills (26 CFR 54.9816–7T, 29 CFR 2590.716–7)

The No Surprises Act directs the Departments to establish a process to receive complaints regarding violations of the application of the QPA by group health plans and health insurance issuers offering group or individual health coverage, and violations by health care providers, facilities, and providers of air ambulance services of the requirements under sections 2799B–2 and 2799B–3 of the PHS Act. The Departments define a complainant as any individual, or their authorized representative, who files a complaint, as described and defined in these interim final rules. This regulatory action is taken as required by the No Surprises Act, which directs the Departments to create a process for balance billing complaints regarding plans and issuers, and directs HHS to create a process for balance billing complaints regarding providers and facilities.

As discussed earlier in HHS' PRA section, the total burden for all complainants is estimated to be 1,800

hours, with an equivalent annual cost of approximately \$97,452. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. HHS will account for approximately 900 burden hours with an equivalent cost of approximately \$48,726. DOL and the Treasury Department will each account for approximately 450 burden hours with an equivalent cost of approximately \$24,363.

4. ICRs Regarding Opt-In State Balance Bill Process (26 CFR 54.9816–3T, 29 CFR 2590.716–3)

The interim final rules allow plans to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)–(d) of the Code, section 716(a)–(d) of ERISA, and section 2799A–1(a)–(d) of the PHS Act. A plan that has chosen to opt into a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into a specified state law, identify the state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

Currently, there are four states that allow self-insured plans to opt in: Nevada, New Jersey, Washington, and Virginia. According to the Nevada Department of Health and Human Services' 2020 Annual Report, 20 private entities or organizations have elected to participate in the state's balance billing law. In addition, according to the Virginia State Corporation Commission, 231 private self-insured plans in Virginia have elected to participate in the state's balance billing law.²⁰⁸ Furthermore, according to Washington's Office of the Insurance Commissioner, 309 private self-insured plans in Washington have elected to participate in the state's balance billing law.²⁰⁹ DOL does not have data on the number of self-insured plans that have opted into New Jersey's

²⁰⁶ 2022: 62.6 million ERISA-covered policyholders × 14% of covered employees in grandfathered plans × (100% minus 5% newly non-grandfathered plans) × (13% in HMOs + 8% in POSs) * 41.8% = 730,346 notices.

²⁰⁷ 2022: \$0.05 per page * 1/2 pages per notice * 730,346 notices = \$18,259.

²⁰⁸ Virginia State Corporation Commission. <https://scc.virginia.gov/balancebilling#>.

²⁰⁹ Washington's Office of Insurance Commissioner. "Self-Funded Group Health Plans Participating in the Balance Billing Protection Act." <https://www.insurance.wa.gov/self-funded-group-health-plans>.

balance billing law. In order to estimate the number of self-insured plans that have opted into the balance billing law for New Jersey, DOL has scaled Washington's estimate by the number of participants with self-insured ERISA-covered plans.²¹⁰ According to the 2019 Health Insurance Coverage Bulletin, there are respectively, 0.7 million, 2.1 million, and 2.7 million with self-insured ERISA-covered plans in Nevada, Virginia, and New Jersey. Additionally, according to the Washington's Office of Insurance Commissioner, about 0.5 million self-insured participants have opted into Washington's balance billing law.²¹¹ This results in a total of 6 million participants.²¹² Thus, DOL estimates that 20, 231, 309, and 57 private self-insured plans will opt in respectively in Nevada, Virginia, Washington, and New Jersey, resulting in a total of 617 self-insured plans.²¹³ These plans will incur the one-time burden and cost to include the disclosure in their plan documents in 2022.

DOL estimates that it will take 1 hour for an administrative assistant, with a wage rate of \$55.14, to gather information and review information.²¹⁴ This results in hour burden of 617 hours, with an equivalent cost of \$34,023. DOL estimates that it will take 30 minutes for a benefits manager, with a wage rate of \$134.21, to gather information and review information.²¹⁵ This results in hour burden of 309

hours, with an equivalent cost of \$41,406. In 2022, the total hour burden is 926 hours, with an equivalent cost of \$75,430.

The average number of participants in a self-insured ERISA-covered plan that will opt into the four states' balance billing laws is 9,724.²¹⁶ DOL assumes that only printing and material costs are associated with the disclosure requirement, because the notice can be incorporated into existing plan documents. DOL estimates that the disclosure will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of plan documents will be delivered electronically at minimal cost.²¹⁷ Thus, in 2022, the cost to deliver 66 percent of these disclosures in print is estimated to be approximately \$321.²¹⁸

Thus, the 3-year average hour burden is 309 hours, with an equivalent cost of \$25,143. The 3-year average cost burden is \$107.

5. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A–5(c) of the PHS Act require plans and issuers to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act apply, information in plain language on the provisions in these sections, and sections 2799B–1 and 2799B–2 of the PHS Act, and other applicable state laws on out-of-network balance billing, and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

As discussed earlier in HHS' PRA section, the total burden for all issuers and TPAs will be 6,153 hours with an equivalent cost of \$699,245 in 2021. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted

for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. HHS will account for approximately 3,077 hours with an equivalent cost of approximately \$349,622. DOL and the Treasury Department will each account for approximately 1,539 hours with an equivalent cost of approximately \$174,811.

Starting in 2022, the total burden for all issuers and TPAs is estimated to be 558,778 hours with an equivalent cost of \$21,714,111. The total printing and materials cost for sending 33,526,677 notices by mail will be \$1,676,334 annually. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. Thus, HHS will account for 279,389 hours, with an equivalent cost of \$10,857,056, and printing and materials cost of \$838,167 starting in 2022. DOL and the Treasury Department will each account for 139,695 hours with an equivalent cost of \$419,084.

Thus, the 3-year average hour burden associated with this requirement for DOL and the Treasury Department is 93,643 hours each with an equivalent cost of \$7,354,578. The 3-year average cost burden for DOL and Treasury is \$279,389 each.

The summary of burden below encompasses the following ICRs: (1) Information to be Shared about the QPA (26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d)), (2) Complaints Process for Surprise Medical Bills (26 CFR 54.9816–7T, 29 CFR 2590.716–7), (3) Opt-In State Balance Bill Process (26 CFR 54.9816–3T, 29 CFR 2590.716–3), and (4) Plan and Issuer Disclosure on Patient Protections Against Balance Billing.

Summary of Burden

Type of Review: New Collection.

Agency: DOL–EBSA, Treasury.

Title: No Surprise Billing.

OMB Numbers: 1210–NEW, 1545–NEW.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Total Respondents: DOL—1,985; Treasury—1,779.

Total Responses: DOL—10,368,277; Treasury—10,368,071.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 927,652 (DOL—463,980, Treasury—463,672).

²¹⁰ Nevada Department of Health and Human Services' Office of Consumer Health Assistance. "Payment for Medically Necessary Emergency Services Provided Out-of-Network 2020 Annual Report." (2020). <https://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/Programs/CHA/AB469%20LCB%20Annual%20Report%202020.pdf>.

²¹¹ Washington's Office of Insurance Commissioner. "Self-Funded Group Health Plans Participating in the Balance Billing Protection Act." <https://www.insurance.wa.gov/self-funded-group-health-plans>.

²¹² Employee Benefits Security Administration. "Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2019 Annual Social and Economic Supplement to the Current Population Survey." (2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

²¹³ New Jersey: $335 \times (0.5/2.7) = 62$ self-insured plans; 62 self-insured plans—5 non-federal self-insured plans = 57 private self-insured plans.

²¹⁴ For more information on how the Department estimates labor costs see: <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.

²¹⁵ For more information on how the Department estimates labor costs see: <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.

²¹⁶ $(6,000,000 \text{ participants with self-insured ERISA-covered plans}) / 617 \text{ self-insured ERISA-covered plans} = 9,724 \text{ participants per self-insured ERISA-covered plan}$.

²¹⁷ According to data from the National Telecommunications and Information Agency, 34 percent of households in the United States accessed health records or health insurance online. <https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show>.

²¹⁸ $9,724 \text{ participants} \times 0.66 \times \$0.05 = \$321$.

Estimated Total Annual Burden Cost: \$558,885 (DOL—\$279,496, Treasury—\$279,389).

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), (5 U.S.C. 601 *et seq.*), requires agencies to analyze options for regulatory relief of small entities to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities. Individuals and states are not included in the definition of a small entity. These interim final rules are not preceded by a general notice of proposed rulemaking, and thus the requirements of RFA do not apply.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule or any final rule for which a general notice of proposed rulemaking was published that includes any Federal mandate that may result in expenditures in any 1 year by state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$158 million. These interim final rules were not preceded by a general notice of proposed rulemaking, and thus the requirements of UMRA do not apply.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by federal agencies in formulating and implementing policies that have “substantial direct effects” on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must

consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the interim final rules.

These interim final rules protect participants, beneficiaries, or enrollees in group health plans and group and individual health insurance coverage, and covered individuals in FEHB plans, from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances. A number of states currently have laws related to surprise medical bills. The Departments are of the view that Congress did not intend to supplant state laws regarding balance billing, but rather to supplement such laws. The provisions in these interim final rules are consistent with the statute’s general approach of supplementing state law. In addition, the No Surprises Act and these interim final rules recognize states’ traditional role as the primary regulators of health insurance issuers, providers, and facilities. The No Surprises Act authorizes states to enforce the new requirements regarding health insurance coverage, including those related to balance billing, with respect to issuers, providers, facilities, and providers of air ambulance services, with HHS enforcing only in cases where the state has notified HHS that the state does not have the authority to enforce or is not otherwise enforcing, or HHS has made a determination that a state has failed to substantially enforce the requirements.

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, the Departments have 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 a state-by-state basis. In addition, the Departments consulted with the NAIC, as required by the No Surprises Act, to establish the geographic regions to be used in the methodology for calculating the QPA.

OPM concluded that it would be inappropriate for FEHB plans to adopt varying state standards, and consistent with the FEHBA, it would adopt state laws where appropriate pursuant to bilaterally negotiated FEHB contracts.

While developing these interim final rules, the Departments attempted to balance the states’ interests in regulating

health insurance issuers, providers, and facilities with the need to ensure at least the minimum federal consumer protections in every state. By doing so, the Departments complied with the requirements of Executive Order 13132.

I. Congressional Review Act

These interim final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and to the Comptroller General for review in accordance with such provisions.

Statutory Authority

The Office of Personnel Management regulations are adopted pursuant to the authority contained in 5 U.S.C. 8902(p) and 5 U.S.C. 8913.

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792, 2794, 2799A–1 through 2799B–9 of the PHS Act (42 U.S.C. 300gg–300gg–63, 300gg–91, 300gg–92, 300gg–94, 300gg–300gg139), as amended; sections 1311 and 1321 of the ACA (42 U.S.C. 13031 and 18041).

List of Subjects

5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Military personnel, Reporting and recordkeeping requirements, Retirement.

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 149

Balance billing, Health care, Health insurance, Reporting and recordkeeping requirements, Surprise billing, State regulation of health insurance, Transparency in coverage.

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.

Laurie Bodenheimer,

Associate Director, Healthcare and Insurance Office of Personnel Management.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Mark J. Mazur,

Acting Assistant Secretary of the Treasury (Tax Policy).

Ali Khawar,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Office of Personnel Management

For the reasons stated in the preamble, the Office of Personnel Management amends 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.102 also issued under sections 11202(f), 11232(e), and 11246 (b) of Pub. L. 105–33, 111 Stat. 251; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521 (36 U.S.C. 5522); Sec. 890.112 also issued under

section 1 of Pub. L. 110–279, 122 Stat. 2604 (2 U.S.C. 2051); Sec. 890.113 also issued under section 1110 of Pub. L. 116–92, 133 Stat. 1198 (5 U.S.C. 8702 note); Sec. 890.301 also issued under section 311 of Pub. L. 111–3, 123 Stat. 64 (26 U.S.C. 9801); Sec. 890.302(b) also issued under section 1001 of Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029 (42 U.S.C. 300gg–14); Sec. 890.803 also issued under 50 U.S.C. 3516 (formerly 50 U.S.C. 403p) and 22 U.S.C. 4069c and 4069c–1; subpart L also issued under section 599C of Pub. L. 101–513, 104 Stat. 2064 (5 U.S.C. 5561 note), as amended; and subpart M also issued under section 721 of Pub. L. 105–261 (10 U.S.C. 1108), 112 Stat. 2061.

Subpart A—Administration and General Provisions

■ 2. Section 890.107 is amended by adding paragraph (e) to read as follows:

§ 890.107 Court review.

* * * * *

(e) A suit for equitable relief founded on 5 U.S.C. chapter 89 that is based on 5 U.S.C. 8902(p) and is governed by 5 CFR part 890 must be brought against OPM by December 31 of the 3rd year after the year in which disputed services were rendered.

■ 3. Section 890.114 is added to subpart A to read as follows:

§ 890.114 Surprise billing.

(a) A carrier must comply with requirements described in 26 CFR 54.9816–3T through 54.9816–6T, 54.9817–1T, and 54.9822–1T, 29 CFR 2590.716–3 through 2590.716–6, 2590.717–1, and 2590.722, and 45 CFR 149.30, 149.110 through 149.140, and 149.310 in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5 U.S.C. 8902(m)(1), and the provisions of the carrier's contract. For purposes of application of such sections, all carriers are deemed to offer health benefits in the large group market.

(b) For purposes of the provisions referenced in paragraph (a) of this section:

Group health plan or plan shall mean a “health benefits plan” defined at 5 U.S.C. 8901(6), which is a Federal governmental plan offered pursuant to 5 U.S.C. chapter 89.

Health insurance issuer or issuer shall include a carrier defined at 5 U.S.C. 8901(7). Where the carrier for a health benefits plan is a voluntary association, an association of organizations or entities, or is otherwise comprised of multiple entities, each entity is responsible for compliance in the same manner as such sections apply to group

health plans and issuers. If and to the extent an entity offering a health benefits plan under 5 U.S.C. chapter 89 is licensed under state law and is properly considered an issuer as defined at section 2791 of the Public Health Service Act, the entity is considered a carrier to the extent of its FEHB health benefits plan contractual and regulatory compliance.

Participant, beneficiary, or enrollee shall include an “enrollee” or “covered individual” as defined by 5 CFR 890.101, as appropriate.

(c) When a complaint challenges a carrier's action or inaction with respect to the surprise billing provisions, OPM will coordinate with the Departments of Health and Human Services, Labor, and the Treasury to resolve the complaint.

Department of the Treasury**Internal Revenue Service**

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 4.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ **Par. 5.** Section 54.9801–1T is added to read as follows:

§ 54.9801–1T Basis and scope (temporary).

(a) *Statutory basis.* This section and §§ 54.9801–2 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9802–3T, 54.9802–4, 54.9811–1, 54.9812–1, 54.9815–1251, 54.9815–2704, 54.9815–2705, 54.9815–2708, 54.9815–2711, 54.9815–2712, 54.9815–2713, 54.9815–2713A, 54.9815–2714, 54.9815–2715, 54.9815–2715A1, 54.9815–2715A2, 54.9815–2715A3, 54.9815–2719, 54.9815–2715A, 54.9816–1 through 9816–7, 54.9831–1, and 54.9833–1 implement Chapter 100 of Subtitle K of the Internal Revenue Code of 1986.

(b) *Scope.* A group health plan or health insurance issuer offering group health insurance coverage may provide greater rights to participants and beneficiaries than those set forth in the portability and market reform sections of this part. This part sets forth minimum requirements for group health plans and group health insurance issuers offering group health insurance coverage concerning certain consumer protections of the Health Insurance Portability and Accountability Act (HIPAA), including special enrollment periods and the prohibition against

discrimination based on a health factor, as amended by the Patient Protection and Affordable Care Act (Affordable Care Act). Other consumer protection provisions, including other protections provided by the Affordable Care Act, the Mental Health Parity and Addiction Equity Act, and the No Surprises Act are set forth in this part.

(c) *Similar requirements under the Employee Retirement Income Security Act and the Public Health Service Act.* Sections 701, 702, 703, 711, 712, 716, 717, 732, and 733 of the Employee Retirement Income Security Act of 1974 and sections 2701, 2702, 2704, 2705, 2721, 2791, 2799A–1, and 2799A–2 of the Public Health Service Act impose requirements similar to those imposed under Chapter 100 of Subtitle K with respect to health insurance issuers offering group health insurance coverage. See 29 CFR part 2590 and 45 CFR parts 144, 146, 148, and 149. See also part B of Title XXVII of the Public Health Service Act and 45 CFR parts 148 and 149 for other rules applicable to health insurance offered in the individual market (defined in § 54.9801–2).

■ **Par. 6.** Section 54.9801–2T is added to read as follows:

§ 54.9801–2T Definitions (temporary).

Unless otherwise provided, the definitions in this section and § 54.9801–2 govern in applying the provisions of sections 9801 through 9825 and 9831 through 9834.

Affiliation period means a period of time that must expire before health insurance coverage provided by an HMO becomes effective, and during which the HMO is not required to provide benefits.

COBRA definitions:

(1) *COBRA* means title X of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(2) *COBRA continuation coverage* means coverage, under a group health plan, that satisfies an applicable COBRA continuation provision.

(3) *COBRA continuation provision* means section 4980B (other than paragraph (f)(1) of section 4980B insofar as it relates to pediatric vaccines), sections 601–608 of ERISA, or title XXII of the PHS Act.

(4) *Exhaustion of COBRA continuation coverage* means that an individual's COBRA continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An

individual is considered to have exhausted COBRA continuation coverage if such coverage ceases—

(i) Due to the failure of the employer or other responsible entity to remit premiums on a timely basis;

(ii) When the individual no longer resides, lives, or works in the service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other COBRA continuation coverage available to the individual; or

(iii) When the individual incurs a claim that would meet or exceed a lifetime limit on all benefits and there is no other COBRA continuation coverage available to the individual.

Condition means a *medical condition*.

Creditable coverage means *creditable coverage* within the meaning of § 54.9801–4(a).

Dependent means any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant.

Employee Retirement Income Security Act of 1974 (ERISA) means the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*).

Enroll means to become covered for benefits under a group health plan (that is, when coverage becomes effective), without regard to when the individual may have completed or filed any forms that are required in order to become covered under the plan. For this purpose, an individual who has health coverage under a group health plan is enrolled in the plan regardless of whether the individual elects coverage, the individual is a dependent who becomes covered as a result of an election by a participant, or the individual becomes covered without an election.

Enrollment date means the first day of coverage or, if there is a waiting period, the first day of the waiting period. If an individual receiving benefits under a group health plan changes benefit packages, or if the plan changes group health insurance issuers, the individual's enrollment date does not change.

Excepted benefits means the benefits described as excepted in § 54.9831(c).

First day of coverage means, in the case of an individual covered for benefits under a group health plan, the first day of coverage under the plan and, in the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy or contract.

Genetic information has the meaning given the term in § 54.9802–3T(a)(3).

Group health insurance coverage means health insurance coverage offered in connection with a group health plan. Individual health insurance coverage reimbursed by the arrangements described in 29 CFR 2510.3–1(l) is not offered in connection with a group health plan, and is not group health insurance coverage, provided all the conditions in 29 CFR 2510.3–1(l) are satisfied.

Group health plan or *plan* means a *group health plan* within the meaning of § 54.9831–1(a).

Group market means the market for health insurance coverage offered in connection with a group health plan. (However, certain very small plans may be treated as being in the *individual market*, rather than the group market; see the definition of individual market in this section.)

Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and short-term, limited-duration insurance. However, benefits described in § 54.9831(c)(2) are not treated as benefits consisting of medical care.

Health insurance issuer or *issuer* means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA). Such term does not include a group health plan.

Health maintenance organization or *HMO* means—

(1) A federally qualified health maintenance organization (as defined in section 1301(a) of the PHS Act);

(2) An organization recognized under State law as a health maintenance organization; or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited-duration insurance. Individual health insurance coverage can include dependent coverage.

Individual market means the market for health insurance coverage offered to individuals other than in connection

with a group health plan. Unless a State elects otherwise in accordance with section 2791(e)(1)(B)(ii) of the PHS Act, such term also includes coverage offered in connection with a group health plan that has fewer than two participants who are current employees on the first day of the plan year.

Issuer means a *health insurance issuer*.

Late enrollee means an individual whose enrollment in a plan is a late enrollment.

Late enrollment means enrollment of an individual under a group health plan other than on the earliest date on which coverage can become effective for the individual under the terms of the plan; or through special enrollment. (For rules relating to special enrollment, see § 54.9801–6.) If an individual ceases to be eligible for coverage under a plan, and then subsequently becomes eligible for coverage under the plan, only the individual's most recent period of eligibility is taken into account in determining whether the individual is a late enrollee under the plan with respect to the most recent period of coverage. Similar rules apply if an individual again becomes eligible for coverage following a suspension of coverage that applied generally under the plan.

Medical care has the meaning given such term by section 213(d), determined without regard to section 213(d)(1)(C) and so much of section 213(d)(1)(D) as relates to qualified long-term care insurance.

Medical condition or *condition* means any condition, whether physical or mental, including, but not limited to, any condition resulting from illness, injury (whether or not the injury is accidental), pregnancy, or congenital malformation. However, genetic information is not a condition.

Participant means *participant* within the meaning of section 3(7) of ERISA.

Placement, or being placed, for adoption means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child's adoption. The child's placement for adoption with such person ends upon the termination of such legal obligation.

Plan year means the year that is designated as the plan year in the plan document of a group health plan, except that if the plan document does not designate a plan year or if there is no plan document, the plan year is—

(1) The deductible or limit year used under the plan;

(2) If the plan does not impose deductibles or limits on a yearly basis, then the plan year is the policy year;

(3) If the plan does not impose deductibles or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, then the plan year is the employer's taxable year; or

(4) In any other case, the plan year is the calendar year.

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

Public health plan means *public health plan* within the meaning of § 54.9801–4(a)(1)(ix).

Public Health Service Act (PHS Act) means the Public Health Service Act (42 U.S.C. 201, *et seq.*).

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 1, excluding the heading "Notice 1," with any additional information required by applicable state law:

Notice 1

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 2, excluding the heading "Notice 2," with any additional information required by applicable state law:

Notice 2

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

(4) If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect.

Significant break in coverage means a *significant break in coverage* within the meaning of § 54.9801–4(b)(2)(iii).

Special enrollment means enrollment in a group health plan under the rights described in § 54.9801–6 or in group health insurance coverage under the rights described in 29 CFR 2590.701–6 or 45 CFR 146.117.

State health benefits risk pool means a *State health benefits risk pool* within the meaning of § 54.9801–4(a)(1)(vii).

Travel insurance means insurance coverage for personal risks incident to planned travel, which may include, but is not limited to, interruption or cancellation of trip or event, loss of baggage or personal effects, damages to accommodations or rental vehicles, and sickness, accident, disability, or death occurring during travel, provided that the health benefits are not offered on a stand-alone basis and are incidental to other coverage. For this purpose, the term travel insurance does not include major medical plans that provide comprehensive medical protection for travelers with trips lasting 6 months or longer, including, for example, those working overseas as an expatriate or military personnel being deployed.

Waiting period means *waiting period* within the meaning of § 54.9815–2708(b).

■ **Par. 7.** Section 54.9815–2719AT is added to read as follows:

§ 54.9815–2719AT Patient protections (temporary).

(a)–(b) [Reserved]

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning before January 1, 2022. *See also* §§ 54.9816–4T through 54.9816–7T, 54.9817–1T, and 54.9822–1T for rules applicable with respect to plan years beginning on or after January 1, 2022.

■ **Par. 8.** Sections 54.9816–1T, 54.9816–2T, 54.9816–3T, 54.9816–4T, 54.9816–5T, 54.9816–6T, 54.9816–7T, 54.9817–1T, and 54.9822–1T are added to read as follows:

Sec.

- 54.9816–1T Basis and scope (temporary).
- 54.9816–2T Applicability (temporary).
- 54.9816–3T Definitions (temporary).
- 54.9816–4T Preventing surprise medical bills for emergency services (temporary).
- 54.9816–5T Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities (temporary).
- 54.9816–6T Methodology for calculating qualifying payment amount (temporary).
- 54.9816–7T Complaints process for surprise medical bills regarding group health plans (temporary).
- 54.9817–1T Preventing surprise medical bills for air ambulance services (temporary).
- 54.9822–1T Choice of health care professional (temporary).

* * * * *

§ 54.9816–1T Basis and scope (temporary).

(a) *Basis.* This section and §§ 54.9816–2T through 54.9816–7T, 54.9817–1T, and 54.9822–1T implement subchapter B of chapter 100 of the Internal Revenue Code of 1986.

(b) *Scope.* This part establishes standards for group health plans with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 54.9816–2T Applicability (temporary).

(a) *In general.* The requirements in §§ 54.9816–4T through 54.9816–7T, 54.9817–1T, and 54.9822–1T apply to group health plans (including grandfathered health plans as defined in § 54.9815–1251T), except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 54.9816–4T through 54.9816–7T, 54.9817–1T, and 54.9822–1T do not apply to the following:

- (1) Excepted benefits as described in § 54.9831–1(c).
- (2) Short-term, limited-duration insurance as defined in § 54.9801–2.
- (3) Health reimbursement arrangements or other account-based group health plans as described in § 54.9815–2711(d).

§ 54.9816–3T Definitions (temporary).

The definitions in § 54.9801–2T apply to §§ 54.9816–4T through 54.9816–7T, 54.9817–1T, and 54.9822–1T unless otherwise specified. In addition, for purposes of §§ 54.9816–4T through 54.9816–7T, 54.9817–1T, and 54.9822–1T, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 54.9816–4T(c)(1).

Emergency services has the meaning given the term in § 54.9816–4T(c)(2).

Health care facility, with respect to a group health plan, in the context of non-emergency services, is each of the following:

- (1) A hospital (as defined in section 1861(e) of the Social Security Act);
- (2) A hospital outpatient department;
- (3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and
- (4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

- (1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and
- (2) Provides any emergency services as described in § 54.9816–4T(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 54.9816–4T(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan, with respect to the furnishing of an item or service under the plan.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan, with respect to the furnishing of an item or service under the plan.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 54.9816–4T, 54.9816–5T, and 54.9817–1T are provided or covered, a written notice from the plan to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503–1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

- (1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan under § 54.9816–4T(b)(3)(iv)(A), § 54.9816–5T(c)(3), or § 54.9817–1T(b)(4)(i); 29 CFR 2590.716–4(b)(3)(iv)(A), 2590.716–5(c)(3), or 2590.717–1(b)(4)(i); or 45 CFR 149.110(b)(3)(iv)(A), 149.120(c)(3), or 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A–1(c) or 2799A–2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 54.9816–4T(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan. A single case agreement between an emergency facility and a plan that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan setting forth the terms

and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan. A single case agreement between a health care facility and a plan that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 54.9816–6T(a)(13).

Service code has the meaning given the term in § 54.9816–6T(a)(14).

Qualifying payment amount has the meaning given the term in § 54.9816–6T(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 54.9816–6T); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for

determining the total amount payable under a group health plan to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts into such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

§ 54.9816–4T Preventing surprise medical bills for emergency services (temporary).

(a) *In general.* If a group health plan provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan payment must be made in accordance with the timing requirement described in section 9816(c)(6), or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant or beneficiary with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the Public Health Service Act) (as applicable) applied under the plan (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 54.9801–2).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a

hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.*

(A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(1) For which benefits are provided or covered under the plan; and

(2) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant or beneficiary is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in 45 CFR 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9816–5T Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities (temporary).

(a) *In general.* If a group health plan provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant or beneficiary

by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of 45 CFR 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan payment must be made in accordance with the timing requirement described in section 9816(c)(6) or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant or beneficiary toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the Public Health Service Act) (as applicable) applied under the plan (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such

cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9816–6T Methodology for calculating qualifying payment amount (temporary).

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 54.9815–2715A1.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—
(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid

program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

(i) An emergency department of a hospital; or

(ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan, the first year after 2019 for which coverage for such item or service is offered under that plan.

(6) *First sufficient information year* means, with respect to a group health plan—

(i) In the case of an item or service for which the plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan for which the plan has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item

or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 54.9815–2711(d)(6)(i), and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more

specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan, but that is offered under the plan in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan consistent with the plan's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan, the amount calculated using the methodology

described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan must—

(A) Calculate separate median contracted rates for CPT code modifiers

“26” (professional component) and “TC” (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.*

(i) If a plan has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount—(1) In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI-U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage

increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:

$$\frac{(\text{CPI-U } 2019/\text{CPI-U } 2018) \times (\text{CPI-U } 2020/\text{CPI-U } 2019) \times (\text{CPI-U } 2021/\text{CPI-U } 2020)}{1}$$

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as CPI-U present year/CPI-U prior year.

(iii) For anesthesia services furnished during 2022, the plan must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(vii) For any other items or services for which a plan generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans.* With respect to a sponsor of a group health plan in a geographic region in which the sponsor did not offer any group health plan during 2019—

(i) For the first year in which the group health plan is offered in such region—

(A) If the plan has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan and furnished during the first year; and

(B) If the plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan is offered in the region, the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan that does not have sufficient

information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan through use of any eligible database, and then increasing that rate by the percentage increase in the CPI-U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan), the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan, the plan must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2022’ is treated as a

reference to furnished during such first sufficient information year, the reference to ‘in 2019’ is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan, the plan must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2023 or a subsequent year’ is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan), the plan must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan reimburses for the item or service billed under the new service code compared to the rate that the plan reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying

payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With an initial payment or notice of denial of payment under § 54.9816–4T, § 54.9816–5T, or § 54.9817–1T:

(i) The qualifying payment amount for each item or service involved;

(ii) A statement to certify that, based on the determination of the plan—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iii) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a

determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(iv) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan is responsible for any costs associated with accessing such database.

(f) *Audits.* See 45 CFR 149.140(f) for audit procedures that apply with respect to ensuring that a plan is in compliance with the requirement of applying a qualifying payment amount under §§ 54.9816–4T, 54.9816–5T, 54.9817–1T, and this section, and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9816–7T Complaints process for surprise medical bills regarding group health plans (temporary).

See 45 CFR 149.150 for the process to receive and resolve complaints that a specific group health plan may be failing to meet the requirement of applying a qualifying payment amount under §§ 54.9816–4T, 54.9816–5T, 54.9816–6T, and 54.9817–1T, which may warrant an investigation.

§ 54.9817–1T Preventing surprise medical bills for air ambulance services (temporary).

(a) *In general.* If a group health plan provides or covers any benefits for air ambulance services, the plan must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with § 54.9816–6T) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the Public Health Service Act) (as applicable) applied under the plan (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan payment must be made in accordance with the timing requirement described in section 9817(b)(6), or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9822–1T Choice of health care professional (temporary).

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this

section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of this paragraph (a).

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan and is available to accept the child. In such a case, the plan must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1*—(1) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network and is available to accept the child.

(2) *Conclusion.* In this *Example 1*, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2*—(1) *Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that A takes A's child to B for treatment of the child's severe shellfish allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(2) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies

is in accordance with the terms of A's coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan may require such a professional to agree to otherwise adhere to the plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan is described in this paragraph (a)(3) if the plan—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan involved from requiring that the obstetrical or gynecological provider notify the primary care health care

professional or the plan of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(2) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that A seeks gynecological services from C, an out-of-network provider.

(2) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(2) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(2) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—(i) In general.* If a group health plan requires the designation by a participant or beneficiary of a primary care provider, the plan must provide a notice informing each participant of the terms of the plan regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan provides a participant with a summary plan description or other similar description of benefits under the plan.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans that require or allow for the designation of primary care providers by participants or beneficiaries, insert:

[Name of group health plan] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator] at [insert contact information].

(B) For plans that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan] or from any other person (including a primary care

provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS.

■ 9. The authority citation for part 2590 is revised to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 10. Section 2590.715–2719A is amended by revising paragraph (c) to read as follows:

§ 2590.715–2719A Patient protections.

* * * * *

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning before January 1, 2022. *See also* §§ 2590.716–4 through 2590.716–7, 2590.717–1, and 2590.722 of this part for rules applicable with respect to plan years beginning on or after January 1, 2022.

Subpart D [Redesignated as Subpart E]

■ 11. Redesignate subpart D as subpart E and add a new subpart D to read as follows:

Subpart D—Surprise Billing and Transparency Requirements

Sec.

- 2590.716–1 Basis and scope.
- 2590.716–2 Applicability.
- 2590.716–3 Definitions.
- 2590.716–4 Preventing surprise medical bills for emergency services.
- 2590.716–5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.
- 2590.716–6 Methodology for calculating qualifying payment amount.
- 2590.716–7 Complaints process for surprise medical bills regarding group health plans and group health insurance coverage.
- 2590.717–1 Preventing surprise medical bills for air ambulance services.
- 2590.722 Choice of health care professional.

Subpart D—Surprise Billing and Transparency Requirements

§ 2590.716–1 Basis and scope.

(a) *Basis.* Sections 2590.716–1 through 2590.722 implement section 716–722 of ERISA.

(b) *Scope.* This part establishes standards for group health plans and health insurance issuers offering group health insurance coverage with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 2590.716–2 Applicability.

(a) *In general.* The requirements in §§ 2590.716–4 through 2590.716–7, 2590.717–1, and 2590.722 apply to group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715–1251), except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 2590.716–4 through 2590.716–7, 2590.717–1, and 2590.722 do not apply to the following:

- (1) Excepted benefits as described in § 2590.732.
- (2) Short-term, limited-duration insurance as defined in § 2590.701–2.
- (3) Health reimbursement arrangements or other account-based group health plans as described in § 2590.715–2711(d).

§ 2590.716–3 Definitions.

The definitions in this part apply to §§ 2590.716 through 2590.722, unless otherwise specified. In addition, for purposes of §§ 2590.716 through 2590.722, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR

414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 2590.716–4(c)(1).

Emergency services has the meaning given the term in § 2590.716–4(c)(2).

Health care facility, with respect to a group health plan or group health insurance coverage, in the context of non-emergency services, is each of the following:

- (1) A hospital (as defined in section 1861(e) of the Social Security Act);
- (2) A hospital outpatient department;
- (3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and
- (4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

- (1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and
- (2) Provides any emergency services as described in § 2590.716–4(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 2590.716–4(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan or group health

insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 2590.716–4, 2590.716–5, and 2590.717–1 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in § 2560.503–1 of this chapter.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816–4T(b)(3)(iv)(A), 54.9816–5T(c)(3), or 54.9817–1T(b)(4)(i); § 2590.716–4(b)(3)(iv)(A), § 2590.716–5(c)(3), or § 2590.717–1(b)(4)(i); or 45 CFR 149.110(b)(3)(iv)(A), 149.120(c)(3), or 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A–1(c) or 2799A–2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or

nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 2590.716–4(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan or coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under

applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 2590.716–6(a)(13).

Service code has the meaning given the term in § 2590.716–6(a)(14).

Qualifying payment amount has the meaning given the term in § 2590.716–6(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 2590.716–6); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group health insurance coverage offered by a health insurance issuer to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of ERISA). A group health plan that opts into such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the

Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

§ 2590.716–4 Preventing surprise medical bills for emergency services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider

or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 716(c)(6) of ERISA, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant or beneficiary with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 2590.701–2).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.*

(A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(1) For which benefits are provided or covered under the plan or coverage; and

(2) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant or beneficiary is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in 45 CFR 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716–5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant or beneficiary by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of 45 CFR 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is

transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 716(c)(6) of ERISA, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant or beneficiary toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716–6 Methodology for calculating qualifying payment amount.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of

this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant or beneficiary in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 2590.715–2715A1.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

(i) An emergency department of a hospital; or

(ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of

Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 2590.715–2711(d)(6)(i), and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for

the item or service, when that rate is different from the contracted rate.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all group health insurance coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers “26” (professional component) and “TC” (technical component);

(B) For anesthesia services, calculate a median contracted rate for the

anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount—(1) In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI-U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:

$$(\text{CPI-U } 2019 / \text{CPI-U } 2018) \times (\text{CPI-U } 2020 / \text{CPI-U } 2019) \times (\text{CPI-U } 2021 / \text{CPI-U } 2020)$$

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as CPI-U present year/CPI-U prior year.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that

service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan or group health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan or group health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying

payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI-U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent

year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2022’ is treated as a reference to furnished during such first sufficient information year, the reference to ‘in 2019’ is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2023 or a subsequent year’ is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for

the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under § 2590.716–4, § 2590.716–5, or § 2590.717–1 of this part:

(i) The qualifying payment amount for each item or service involved;

(ii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's or beneficiary's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iii) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(iv) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code;

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any

costs associated with accessing such database.

(f) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716–7 Complaints process for surprise medical bills regarding group health plans and group health insurance coverage.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group health insurance coverage may be failing to meet the requirements under subpart D of this part, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart D of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) DOL will consider the date a complaint is filed to be the date upon which DOL receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) DOL will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. DOL will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaint resolution process. As part of the response, DOL may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance,

membership booklet, outline of coverage, or other evidence of coverage the plan or issuer provides to participants or beneficiaries;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information DOL may need to make a determination of facts for an investigation.

(3) DOL will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by DOL. A complaint is considered processed after DOL has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint and the plan or issuer involved, DOL may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if DOL receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

§ 2590.717–1 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan or a health insurance issuer offering group health insurance coverage provides or covers any benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with

§ 2590.716–6) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 717(b)(6) of ERISA, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.722 Choice of health care professional.

(a) *Choice of health care professional—(1) Designation of primary care provider—(i) In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who

is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider—(i) In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of

coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network and is available to accept the child.

(2) *Conclusion.* In this *Example 1*, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that A takes A's child to B for treatment of the child's severe shellfish allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(2) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) *Patient access to obstetrical and gynecological care—(i) General rights—*

(A) *Direct access.* A group health plan, or a health insurance issuer offering group health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior

authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(2) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care

provider prior to obtaining gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that A seeks gynecological services from C, an out-of-network provider.

(2) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(2) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(2) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—(i) In general.* If a group health plan or health insurance issuer requires the designation by a participant or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, or beneficiaries, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in

obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

Department of Health and Human Services

45 CFR Subtitle A, Subchapter B

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 149, and 156 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 12. The authority citation for part 144 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, and 300gg-111 through 300gg-139, as amended.

■ 13. Section 144.101 is amended by:

■ a. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively; and

■ b. Adding new paragraph (d).

The addition reads as follows:

§ 144.101 Basis and purpose.

* * * * *

(d) Part 149 of this subchapter implements the provisions of parts D and E of title XXVII of the PHS Act that apply to group health plans, health insurance issuers in the group and individual markets, health care providers and facilities, and providers of air ambulance services.

* * * * *

■ 14. Section 144.102 is revised to read as follows:

§ 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 149, all health insurance coverage is generally divided into two markets—the group market and the individual market. The group market is further divided into the large group market and the small group market.

(b) The protections afforded under 45 CFR parts 144 through 149 to individuals and employers (and other sponsors of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the individual market.

(c) Coverage that is provided to associations, but not related to employment, and sold to individuals is not considered group coverage under 45

CFR parts 144 through 149. If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered individual health insurance coverage for purposes of 45 CFR parts 144 through 149. The coverage is considered coverage in the individual market, regardless of whether it is considered group coverage under state law. If the health insurance coverage is offered in connection with a group health plan as defined at 45 CFR 144.103, it is considered group health insurance coverage for purposes of 45 CFR parts 144 through 149.

(d) Provisions relating to CMS enforcement of parts 146, 147, 148, and 149 are contained in part 150 of this subchapter.

■ 15. Section 144.103 is amended by revising the introductory text to read as follows:

§ 144.103 Definitions.

For purposes of parts 146 (group market), 147 (group and individual market), 148 (individual market), 149 (surprise billing and transparency), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 16. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, and 300gg-111 through 300gg-139, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

■ 17. Section 147.138 is amended by revising paragraph (c) to read as follows:

§ 147.138 Patient protections.

* * * * *

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning before January 1, 2022. *See also* subparts B and D of part 149 of this subchapter for rules applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

■ 18. Add part 149 to read as follows:

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

Subpart A—General Provisions

Sec.

149.10 Basis and scope.

149.20 Applicability.

149.30 Definitions.

Subpart B—Protections against Balance Billing for the Group and Individual Health Insurance Markets

- 149.110 Preventing surprise medical bills for emergency services.
- 149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.
- 149.130 Preventing surprise medical bills for air ambulance services.
- 149.140 Methodology for calculating qualifying payment amount.
- 149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

Subpart C—[Reserved]**Subpart D—Additional Patient Protections**

- 149.310 Choice of health care professional.

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

- 149.410 Balance billing in cases of emergency services.
- 149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.
- 149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.
- 149.440 Balance billing in cases of air ambulance services.
- 149.450 Complaints process for balance billing regarding providers and facilities.

Authority: 42 U.S.C. 300gg–111 through 300gg–139, as amended.

Subpart A—General Provisions**§ 149.10 Basis and scope.**

(a) *Basis.* This part implements parts D and E of title XXVII of the PHS Act.

(b) *Scope.* This part establishes standards for group health plans, health insurance issuers offering group or individual health insurance coverage, health care providers and facilities, and providers of air ambulance services with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 149.20 Applicability.

(a) *In general.* (1) The requirements in subparts B and D of this part apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter), except as specified in paragraph (b) of this section.

(2) The requirements in subpart E of this part apply to health care providers, health care facilities, and providers of air ambulance services.

(b) *Exceptions.* The requirements in subparts B and D of this part do not apply to the following:

(1) Excepted benefits as described in §§ 146.145 and 148.220 of this subchapter.

(2) Short-term, limited-duration insurance as defined in § 144.103 of this subchapter.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 147.126(d) of this subchapter.

§ 149.30 Definitions.

The definitions in part 144 of this subchapter apply to this part, unless otherwise specified. In addition, for purposes of this part, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 149.110(c)(1).

Emergency services has the meaning given the term in § 149.110(c)(2).

Health care facility, with respect to a group health plan or group or individual health insurance coverage, in the context of non-emergency services, is each of the following:

- (1) A hospital (as defined in section 1861(e) of the Social Security Act);
- (2) A hospital outpatient department;
- (3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and
- (4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

- (1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and
- (2) Provides any emergency services as described in § 149.110(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 149.110 through 149.130 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503–1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816–4T(b)(3)(iv)(A), 54.9816–5T(c)(3), or 54.9817–1T(b)(4)(i); 29 CFR 2590.716–4(b)(3)(iv)(A), 2590.716–5(c)(3), or 2590.717–1(b)(4)(i);

or § 149.110(b)(3)(iv)(A), § 149.120(c)(3), or § 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such as agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A–1(c) or 2799A–2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or

enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 149.140(a)(13).

Service code has the meaning given the term in § 149.140(a)(14).

Qualifying payment amount has the meaning given the term in § 149.140(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 149.140); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage offered by a health insurance issuer to

the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts in to such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

Subpart B—Protections Against Balance Billing for the Group and Individual Health Insurance Markets

§ 149.110 Preventing surprise medical bills for emergency services.

(a) **In general.** If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) **Coverage requirements.** A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section

2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 144.103 of this subchapter).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as

required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.*

(A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(1) For which benefits are provided or covered under the plan or coverage; and

(2) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in § 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to items and

services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant, beneficiary, or enrollee by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of § 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified

State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant, beneficiary, or enrollee toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.130 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with § 149.140) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–2(b)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.140 Methodology for calculating qualifying payment amount.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 147.210 of this subchapter.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—
(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

(i) An emergency department of a hospital; or

(ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan or issuer has

sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a

geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or

a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group or individual health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in

paragraph (a)(8)(iv) of this section, if applicable) or all group or individual health insurance coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers “26” (professional component) and “TC” (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.*

(i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount*—(1) *In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI-U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:

$$(\text{CPI-U } 2019 / \text{CPI-U } 2018) \times (\text{CPI-U } 2020 / \text{CPI-U } 2019) \times (\text{CPI-U } 2021 / \text{CPI-U } 2020)$$

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as CPI-U present year/CPI-U prior year.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a

unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of

this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have

sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI-U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such

paragraph to such item or service, the reference to ‘furnished during 2022’ is treated as a reference to furnished during such first sufficient information year, the reference to ‘in 2019’ is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2023 or a subsequent year’ is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service

code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under § 149.110, § 149.120, or § 149.130:

(i) The qualifying payment amount for each item or service involved;

(ii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iii) A statement that if the provider or facility, as applicable, wishes to

initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(iv) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any costs associated with accessing such database.

(f) *Audits.* The procedures described in part 150 of this subchapter apply with respect to ensuring that a plan or coverage is in compliance with the requirement of applying a qualifying payment amount under this subpart and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group or individual health insurance coverage may be failing to meet the requirements under this subpart, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart B of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. As part of the response, HHS may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance, membership booklet, outline of

coverage, or other evidence of coverage the plan or issuer provides to participants, beneficiaries, or enrollees;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information HHS may need to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint and the plan or issuer involved, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

Subpart C—[Reserved]

Subpart D—Additional Patient Protections

§ 149.310 Choice of health care professional.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider—(i) In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network and is available to accept the child.

(2) *Conclusion.* In this *Example 1*, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that A takes A's child to B for treatment of the child's severe shellfish allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(2) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) *Patient access to obstetrical and gynecological care—(i) General rights—*

(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes

in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(2) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that A seeks

gynecological services from *C*, an out-of-network provider.

(2) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(2) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(2) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—(i) In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

§ 149.410 Balance billing in cases of emergency services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished emergency services (for which benefits are provided under the plan or coverage) with respect to an emergency medical condition with respect to a visit at an emergency department of a hospital or an independent freestanding emergency department—

(1) A nonparticipating emergency facility must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for such emergency services (as defined in 26 CFR 54.9816–4T(c)(2), 29 CFR 2590.716–4(c)(2), and § 149.110(c)(2), as applicable) that exceeds the cost-sharing requirement for such services (as determined in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and § 149.110(b)(3)(ii) and (iii), as applicable).

(2) A nonparticipating provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for an emergency service (as defined in 26 CFR 54.9816–4T(c)(2), 29 CFR 2590.716–4(c)(2), and § 149.110(c)(2), as applicable) furnished to such individual by such provider with respect to such emergency medical condition and visit for which the individual receives emergency services at the hospital or independent freestanding emergency department that exceeds the cost-sharing requirement for such service (as determined in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and § 149.110(b)(3)(ii) and (iii), as applicable).

(b) *Notice and consent to be treated by a nonparticipating provider or nonparticipating emergency facility.* The requirements in paragraph (a) of this section do not apply with respect to items and services described in 26 CFR, 54.9816–4T(c)(2)(ii)(A), 29 CFR 2590.716–4(c)(2)(ii)(A), § 149.110(c)(2)(ii)(A), as applicable, and are not included as emergency services if all of the following conditions are met:

(1) The attending emergency physician or treating provider determines that the participant,

beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into account the individual's medical condition. The attending emergency physician's or treating provider's determination is binding on the facility for purposes of this requirement.

(2) The provider or facility furnishing such additional items and services satisfies the notice and consent criteria of § 149.420(c) through (g) with respect to such items and services, provided that the written notice additionally satisfies paragraphs (b)(2)(i) and (ii) of this section, as applicable. In applying this paragraph (b)(2), a reference in § 149.420 to a nonparticipating provider is deemed to include a nonparticipating emergency facility.

(i) In the case of a participating emergency facility and a nonparticipating provider, the written notice must also include a list of any participating providers at the facility who are able to furnish such items and services involved and notification that the participant, beneficiary, or enrollee may be referred, at their option, to such a participating provider.

(ii) In the case of a nonparticipating emergency facility, the written notice must include the good faith estimated amount that the participant, beneficiary, or enrollee may be charged for items or services furnished by the nonparticipating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or services).

(3) The participant, beneficiary, or enrollee (or an authorized representative of such individual) is in a condition to receive the information described in § 149.420, as determined by the attending emergency physician or treating provider using appropriate medical judgment, and to provide informed consent under such section, in accordance with applicable State law. For purposes of this section and § 149.420, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee.

(4) The provider or facility satisfies any additional requirements or prohibitions as may be imposed under State law.

(c) *Inapplicability of notice and consent exception to certain items and services.* A nonparticipating provider or nonparticipating facility specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider or nonparticipating emergency facility satisfied the notice and consent criteria in § 149.420(c) through (g).

(d) *Retention of certain documents.* A nonparticipating emergency facility (with respect to such facility or any nonparticipating provider at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage (or an authorized representative of such an individual) a written consent in accordance with § 149.420(e), with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(e) *Notification to plan or issuer.* In the case of a participant, beneficiary, or enrollee who is stabilized and furnished additional items and services described in § 149.110(c)(2)(ii), a nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer, respectively, when transmitting the bill for such items and services, either on the bill or in a separate document, as to whether all of the conditions described in paragraph (b) of this section are met with respect to each of the items and services for which the bill is submitted, and if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraph (b)(2) of this section.

(f) *Applicability date.* The provisions of this section are applicable with respect to emergency services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.

(a) *In general.* A nonparticipating provider of a group health plan or group or individual health insurance coverage who provides items or services (other than emergency services) for which benefits are provided under the plan or coverage at a participating health care facility must not bill, and must not hold liable, a participant, beneficiary, or enrollee of such plan or coverage for a payment amount for such an item or service furnished by such provider with respect to a visit at the facility that exceeds the cost-sharing requirement for such item or service (as determined in accordance with 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.717–1(c)(1) and (2), and § 149.120(c)(1) and (2), as applicable), unless the provider (or the participating health care facility on behalf of the provider) satisfies the notice and consent criteria of paragraph (c) of this section.

(b) *Inapplicability of notice and consent exception to certain items and services.* The notice and consent criteria in paragraphs (c) through (i) of this section do not apply, and a nonparticipating provider specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to the following services:

(1) Ancillary services, meaning—

(i) Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner;

(ii) Items and services provided by assistant surgeons, hospitalists, and intensivists;

(iii) Diagnostic services, including radiology and laboratory services; and

(iv) Items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility.

(2) Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider satisfied the notice and consent criteria in paragraph (c) of this section.

(c) *Notice and consent to be treated by a nonparticipating provider.* Subject to paragraph (f) of this section, and unless prohibited by State law, a nonparticipating provider satisfies the notice and consent criteria of this paragraph (c) with respect to items or services furnished by the provider to a participant, beneficiary, or enrollee of a group health plan or group or individual

health insurance coverage, if the provider (or a participating health care facility on behalf of a nonparticipating provider)—

(1) Provides to the participant, beneficiary, or enrollee a written notice in paper or, as practicable, electronic form, as selected by the individual, that contains the information required under paragraph (d) of this section, provided such written notice is provided:

(i) In accordance with guidance issued by HHS, and in the form and manner specified in such guidance;

(ii) With the consent document, and is provided physically separate from other documents and not attached to or incorporated into any other document; and

(iii) To such participant, beneficiary, or enrollee—

(A) Not later than 72 hours prior to the date on which the individual is furnished such items or services, in the case where the appointment to be furnished such items or services is scheduled at least 72 hours prior to the date on which the individual is to be furnished such items and services; or

(B) On the date the appointment to be furnished such items or services is scheduled, in the case where the appointment is scheduled within 72 hours prior to the date on which such items or services are to be furnished. Where an individual is provided the notice on the same date that the items or services are to be furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply.

(2) Obtains from the participant, beneficiary, or enrollee the consent described in paragraph (e) of this section to be treated by the nonparticipating provider. An authorized representative may receive the notice on behalf of a participant, beneficiary, or enrollee, and may provide consent on behalf of the participant, beneficiary, or enrollee. For purposes of this section and § 149.410, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. The consent must—

(i) Be provided voluntarily, meaning the individual is able to consent freely, without undue influence, fraud, or duress;

(ii) Be obtained in accordance with, and in the form and manner specified in, guidance issued by HHS; and

(iii) Not be revoked, in writing, by the participant, beneficiary, or enrollee prior to the receipt of items and services to which the consent applies.

(3) Provides a copy of the signed written notice and consent to the participant, beneficiary, or enrollee in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Information required under written notice.* The written notice described in paragraph (c)(1) of this section must be provided in the form and manner specified by HHS in guidance, and must—

(1) State that the health care provider is a nonparticipating provider, with respect to the health plan or coverage.

(2) Include the good faith estimated amount that such nonparticipating provider may charge the participant, beneficiary, or enrollee for the items and services involved (including any item or service that is reasonably expected to be furnished by the nonparticipating provider in conjunction with such items or services), including notification that the provision of the estimate or consent to be treated under paragraph (e) of this section does not constitute a contract with respect to the charges estimated for such items and services or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility.

(3) Provide a statement that prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility.

(4) Clearly state that consent to receive such items and services from such nonparticipating provider is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, with respect to the plan or coverage, as applicable, and that in such cases the cost-sharing responsibility of the participant, beneficiary, or enrollee would not exceed the responsibility that would apply with respect to such an item or service that is furnished by a participating provider, as applicable, with respect to such plan.

(e) *Consent described to be treated by a nonparticipating provider.* The consent described in this paragraph (e), with respect to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage who is to be furnished items or services by a nonparticipating provider, must be documented on a form specified by the

Secretary, in consultation with the Secretary of Labor, through guidance and provided in accordance with such guidance, that must be signed by the participant, beneficiary, or enrollee before such items and services are furnished and that—

(1) Acknowledges in clear and understandable language that the participant, beneficiary, or enrollee has been—

(i) Provided with the written notice under paragraph (c) of this section, in the form selected by the participant, beneficiary, or enrollee.

(ii) Informed that the payment of such charge by the participant, beneficiary, or enrollee might not accrue toward meeting any limitation that the plan or coverage places on cost sharing, including an explanation that such payment might not apply to an in-network deductible or out-of-pocket maximum applied under the plan or coverage.

(2) States that by signing the consent, the individual agrees to be treated by the nonparticipating provider and understands the individual may be balance billed and subject to cost-sharing requirements that apply to services furnished by the nonparticipating provider.

(3) Documents the time and date on which the participant, beneficiary, or enrollee received the written notice described in paragraph (c) of this section and the time and date on which the individual signed the consent to be furnished such items or services by such nonparticipating provider.

(f) *Language access.* (1) A nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) must provide the individual with the choice to receive the written notice and consent document in any of the 15 most common languages in the State in which the applicable facility is located, except that the notice and consent document may instead be available in any of the 15 most common languages in a geographic region that reasonably reflects the geographic region served by the applicable facility; and

(2) If the individual's preferred language is not among the 15 most common languages in which the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) makes the notice and consent document available and the individual cannot understand the language in which the notice and consent document are provided, the notice and consent criteria in paragraph (c) of this section are not met unless the nonparticipating

provider (or the participating health care facility on behalf of the nonparticipating provider) has obtained the services of a qualified interpreter to assist the individual with understanding the information contained in the notice and consent document.

(g) *Scope of consent.* The consent described in paragraph (e) of this section will constitute consent only to the receipt of the information provided pursuant to this section and will not constitute a contractual agreement of the participant, beneficiary, or enrollee to any estimated charge or amount included in such information, or to be treated by that provider or facility.

(h) *Retention of certain documents.* A participating health care facility (with respect to nonparticipating providers at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage a written consent in accordance with paragraph (e) of this section, with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(i) *Notification to plan or issuer.* For each item or service furnished by a nonparticipating provider described in paragraph (a) of this section, the provider (or the participating facility on behalf of the nonparticipating provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility, and, if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraphs (c) and (e) of this section. In instances where, to the extent permitted by this section, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice with the bill to the participant, beneficiary, or enrollee.

(j) *Applicability date.* The provisions of this section are applicable with respect to items and services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.

(a) *In general.* Each health care provider and health care facility (including an emergency department of a hospital and an independent freestanding emergency department) must make publicly available, post on a public website of such provider or facility (if applicable), and provide to any individual who is a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer and to whom the provider or facility furnishes items or services, the information described in paragraph (b) of this section regarding patient protections against balance billing, except as provided in paragraphs (e) and (f) of this section. A provider or facility must make the disclosures in accordance with the method and timing requirements set forth in paragraphs (c) and (d) of this section.

(b) *Content.* The disclosures required under this section must include, in clear and understandable language, all the information described in this paragraph (b) (and may include any additional information that does not conflict with that information).

(1) A statement that explains the requirements of and prohibitions applicable to the health care provider or health care facility under sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations in §§ 149.410 and 149.420;

(2) If applicable, a statement that explains any State law requirements regarding the amounts such provider or facility may, with respect to an item or service, charge a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer with respect to which such provider or facility does not have a contractual relationship, after receiving payment, if any, from the plan or coverage, respectively, for such item or service and any applicable cost-sharing payment from such participant, beneficiary, or enrollee; and

(3) A statement providing contact information for the appropriate State and Federal agencies that an individual may contact if the individual believes the provider or facility has violated a requirement described in the notice.

(c) *Required methods for disclosing information.* Health care providers and health care facilities must provide the disclosure required under this section as follows:

(1) With respect to the required disclosure to be posted on a public website, the information described in paragraph (b) of this section, or a link to such information, must appear on a searchable homepage of the provider's or facility's website. A provider or facility that does not have its own website is not required to make a disclosure under this paragraph (c)(1).

(2) With respect to the required disclosure to the public, a provider or facility must make public the information described in paragraph (b) of this section on a sign posted prominently at the location of the provider or facility. A provider that does not have a publicly accessible location is not required to make a disclosure under this paragraph (c)(2).

(3) With respect to the required disclosure to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a provider or facility must provide the information described in paragraph (b) of this section in a one-page (double-sided) notice, using print no smaller than 12-point font. The notice must be provided in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Timing of disclosure to individuals.* A health care provider or health care facility is required to provide the notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer no later than the date and time on which the provider or facility requests payment from the individual, or with respect to an individual from whom the provider or facility does not request payment, no later than the date on which the provider or facility submits a claim to the group health plan or health insurance issuer.

(e) *Exceptions.* A health care provider is not required to make the disclosures required under this section—

(1) If the provider does not furnish items or services at a health care facility, or in connection with visits at health care facilities; or

(2) To individuals to whom the provider furnishes items or services, if such items or services are not furnished at a health care facility, or in connection with a visit at a health care facility.

(f) *Special rule to prevent unnecessary duplication with respect to health care providers.* To the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency

department of a hospital or independent freestanding emergency department), the provider satisfies the requirements of paragraphs (c)(2) and (3) of this section if the facility makes the information available, in the required form and manner, pursuant to a written agreement. Accordingly, if a provider and facility enter into a written agreement under which the facility agrees to make the information required under this section available on a sign posted prominently at the facility and to provide the one-page notice to individuals in compliance with this section, and the facility fails to do so, then the facility, but not the provider, violates the disclosure requirements of this section.

(g) *Applicability date.* The provisions of this section are applicable beginning on January 1, 2022.

§ 149.440 Balance billing in cases of air ambulance services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer who is furnished air ambulance services (for which benefits are available under such plan or coverage) from a nonparticipating provider of air ambulance services, with respect to such plan or coverage, the provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for the air ambulance services furnished by the provider that is more than the cost-sharing amount for such service (as determined in accordance with 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and § 149.130(b)(1) and (2), as applicable).

(b) *Applicability date.* The provisions of this section are applicable with respect to air ambulance services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.450 Complaint process for balance billing regarding providers and facilities.

(a) *Scope and definitions.*—(1) *Scope.* This section establishes a process for HHS to receive and resolve complaints regarding information that a health care provider, provider of air ambulance services, or health care facility may be failing to meet the requirements under subpart E of this part, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written, or oral, that

indicates there has been a potential violation of the requirements under this subpart, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral, written, or electronic statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. HHS may request additional information that may be needed to process the complaint as part of the response. Such additional information may include:

(i) Health care provider, air ambulance provider, or health care facility bills;

(ii) Health care provider, air ambulance provider, or health care facility network status;

(iii) Information regarding the participant's, beneficiary's, or enrollee's health care plan or health insurance coverage;

(iv) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(v) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(vi) Any other information HHS needs to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the health care provider, air ambulance provider or health care facility;

(iii) Refer the health care provider, air ambulance provider or health care facility for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of resolution and any corrective action taken.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 19. 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.

■ 20. Section 156.155 is amended by:

■ a. Revising paragraph (a)(3);

■ b. Redesignating paragraph (c) as paragraph (d); and

■ c. Adding a new paragraph (c).

The revision and addition read as follows:

§ 156.155 Enrollment in catastrophic plans.

(a) * * *

(3) Provides coverage of the essential health benefits under section 1302(b) of the Affordable Care Act, except that the plan provides no benefits for any plan year (except as provided in paragraphs (a)(4), (b), and (c) of this section) until the annual limitation on cost sharing in section 1302(c)(1) of the Affordable Care Act is reached.

* * * * *

(c) *Coverage to prevent surprise medical bills.* A catastrophic plan must provide benefits as required under sections 2799A–1 and 2799A–2 of the Public Health Service Act and their implementing regulations in §§ 149.110, 149.120, and 149.130 or any applicable State law providing similar protections to individuals, and will not violate paragraph (a)(3) of this section solely because of the provision of such benefits before the annual limitation on cost sharing is reached.

* * * * *

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