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The Code of Federal Regulations is sold by the Superintendent of Documents.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0124]

RIN 3150–AK66

List of Approved Spent Fuel Storage Casks: TN Americas LLC NUHOMS® EOS Dry Spent Fuel Storage System, Certificate of Compliance No. 1042, Amendment No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of October 26, 2021, for the direct final rule that was published in the *Federal Register* on August 12, 2021. The direct final rule amended the TN Americas LLC, NUHOMS® EOS Dry Spent Fuel Storage System listing in the “List of approved spent fuel storage casks” to include Amendment No. 2 to Certificate of Compliance No. 1042. Amendment No. 2 revises the certificate of compliance to add a dry shielded canister for storage, add new heat load zone configurations, and make other changes to the storage system. Amendment No. 2 also changes the certificate of compliance and technical specifications, and updates the final safety analysis report for consistency and clarity.

DATES: The effective date of October 26, 2021, for the direct final rule published August 12, 2021 (86 FR 44262), is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2021–0124 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–2021–0124. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <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 proposed amendment to the certificate of compliance, the proposed changes to the technical specifications, and the preliminary safety evaluation report are available in ADAMS under Package Accession No. ML21125A103. The final amendment to the certificate of compliance, final changes to the technical specifications, and final safety evaluation report also can be viewed in ADAMS under Package Accession No. ML21244A295.

- *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 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Vanessa Cox, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8342, email: Vanessa.Cox@nrc.gov.

SUPPLEMENTARY INFORMATION: On August 12, 2021 (86 FR 44262), the NRC published a direct final rule amending its regulations in part 72 of title 10 of the *Code of Federal Regulations* to revise the TN Americas LLC, NUHOMS® EOS Dry Spent Fuel Storage System listing within the “List of approved spent fuel storage casks” to include Amendment No. 2 to Certificate of Compliance No. 1042. Amendment No. 2 revises the certificate of compliance to add a dry shielded canister for storage, add new heat load zone configurations, and make other changes to the storage system.

Amendment No. 2 also changes the certificate of compliance and technical specifications, and updates the final safety analysis report for consistency and clarity. In the direct final rule published on August 12, 2021, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on October 26, 2021. The NRC did not receive any comments on the direct final rule. Therefore, the direct final rule will become effective as scheduled.

Dated: October 1, 2021.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–21859 Filed 10–6–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0782; Project Identifier MCAI–AD–2021–00915–A; Amendment 39–21732; AD 2021–19–14]

RIN 2120–AA64

Airworthiness Directives; AERO Sp. z o.o. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for AERO Sp. z o.o. (AERO) Model AT–3R100 airplanes with an ELPROP 3–1–1P propeller. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as cracks in the propeller hub. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 27, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 27, 2021.

The FAA must receive comments on this AD by November 22, 2021.

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

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

For service information identified in this final rule, contact AERO AT Sp. z o.o., Dział Serwisu, ul. Wał Miedzeszyński 844, 03-942 Warszawa, Poland; phone: +48 22 616 20 87; fax: +48 22 617 85 28; email: service@at-3.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0782.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0782; 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 MCAI, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329-4059; fax: (816) 329-4090; email: doug.rudolph@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA-2021-0782 and Project Identifier MCAI-2021-00915-A” at the beginning of your comments. The most helpful comments reference a specific portion of the final

rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent Doug Rudolph, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021-0189-E, dated August 9, 2021 (referred to after this as “the MCAI”), to address an unsafe condition on ELPROP 3-1-1P propellers that are installed on, but not limited to, AERO Models AT-3R100 and AT-4LSA airplanes. The MCAI states:

Occurrences have been reported of finding cracks on the propeller hub during service inspections. Cracks were detected on the propeller hub surface, near the blade attachment bolt holes and in the blade root area.

This condition, if not detected and corrected, could lead to loss of the propeller blade with consequent loss of control of the aeroplane.

To address this unsafe condition, AERO issued [mandatory service bulletin] MSB EPB.01.B to provide inspection instructions for certain propellers, and EASA issued Emergency AD 2009-0134-E to require repetitive detailed visual inspections of those propeller hubs and, depending on findings, replacement.

Since that [EASA] AD was issued, additional occurrences were reported of finding propeller hub cracks. Prompted by these findings, AERO issued MSB EPB.02.B applicable to propellers with s/n 3E.089 and higher.

For the reason described above, this [EASA] AD retains the requirements of EASA Emergency AD 2009-0134-E, which is superseded, and expands the Applicability to all propeller s/n.

You may examine the MCAI in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0782.

Related Service Information Under 14 CFR Part 51

The FAA reviewed AERO Mandatory Service Bulletin (MSB) EPB.01.B, Issue 1, dated May 14, 2009, which applies to propellers with serial numbers 3E.001 through 3E.088; and AERO MSB EPB.02.B, Issue 1, dated July 20, 2021, which applies to propellers with serial numbers 3E.089 and larger. This service information specifies procedures for inspecting the propeller hub for cracks and contacting the design approval holder for corrective action. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA’s Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD because it has determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

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

Differences Between This AD and the MCAI

The MCAI applies to the Model AT-4LSA airplane, and this AD does not

because it does not have an FAA type certificate.

Justification for Immediate Adoption and Determination of the Effective Date

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

The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because there are no airplanes currently on the U.S. registry and thus, it is unlikely that the FAA will receive any adverse comments or useful information about this AD from U.S. operators. Accordingly, notice and opportunity for prior public comment are unnecessary pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Costs of Compliance

There are currently no affected airplanes on the U.S. registry. In the event an affected airplane becomes a U.S. registered airplane, the following is an estimate of the costs to comply with this AD.

The FAA estimates that it would take .5 work-hour per airplane to comply with the inspection requirement in this AD. The average labor rate is \$85 per work-hour. Based on these figures, the FAA estimates the cost of this AD to be \$42.50 per airplane, per inspection cycle.

Corrective action if cracks are found would vary significantly from airplane to airplane. Therefore, the FAA is unable to estimate what the cost of corrective action would be per airplane.

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 Flexibility Act

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

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, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021–19–14 AERO Sp. z o.o.: Amendment 39–21732; Docket No. FAA–2021–0782; Project Identifier MCAI–2021–00915–A.

(a) Effective Date

This airworthiness directive (AD) is effective October 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to AERO Sp. z o.o. Model AT–3R100 airplanes, all serial numbers, certificated in any category, with an ELPROP 3–1–1P propeller installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 6114, Propeller Hub Section.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as cracks in the propeller hub. The FAA is issuing this AD to detect and correct cracked propeller hubs, which could lead to loss of the propeller blade with consequent loss of airplane control.

(f) Compliance

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

(g) Inspection and Replacement

(1) Before further flight after the effective date of this AD and thereafter at intervals not to exceed 50 hours time-in-service, inspect the propeller hub for cracks in accordance with paragraphs 5.1, 5.2, and 5.4 of the Instructions in AERO Sp. z o.o. Mandatory Service Bulletin EPB.01.B, Issue 1, dated May 14, 2009; or AERO Sp. z o.o. Mandatory Service Bulletin EPB.02.B, Issue 1, dated July 20, 2021, as applicable to your propeller, except you are not required to contact the manufacturer. If any crack or other discrepancy is found, before further flight, repair using a method approved by the Manager, International Validation Branch, FAA, or the European Union Aviation Safety Agency (EASA).

(2) As of the effective date of this AD, do not install an ELPROP 3–1–1P propeller on any airplane unless the propeller hub has passed the inspection required by paragraph (g)(1) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (i)(1) of this AD or email: 9-AVS-AIR-730-AMOC@faa.gov.

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

(i) Related Information

(1) For more information about this AD, contact Doug Rudolph, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329-4059; fax: (816) 329-4090; email: doug.rudolph@faa.gov.

(2) Refer to EASA AD 2021-0189-E, dated August 9, 2021, for more information. You may examine the EASA AD in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0782.

(j) Material Incorporated by Reference

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

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

(i) AERO Sp. z o.o. Mandatory Service Bulletin EPB.01.B, Issue 1, dated May 14, 2009.

(ii) AERO Sp. z o.o. Mandatory Service Bulletin EPB.02.B, Issue 1, dated July 20, 2021.

(3) For service information identified in this AD, contact AERO AT Sp. z o.o., Dział Serwisu, ul. Wał Miedzeszyński 844, 03-942 Warszawa, Poland; phone: +48 22 616 20 87; fax: +48 22 617 85 28; email: service@at-3.com.

(4) You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0782.

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

Issued on September 7, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-21932 Filed 10-6-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2021-0591; Airspace Docket No. 21-AWP-15]

RIN 2120-AA66

Revocation of Class E Airspace; Creech Air Force Base Airport, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes the Class E airspace extending upward from 700 feet above the surface at Creech Air Force Base (AFB) Airport, Indian Springs, NV. This action also implements several administrative updates to the Class D legal description. **DATES:** Effective 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231-3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that

section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it revokes the Class E airspace at Creech AFB Airport, Indian Springs, NV, to ensure the safety and management of operations at the airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 40790; July 29, 2021) for Docket No. FAA-2021-0591 to revoke the Class E airspace at Creech AFB Airport, Indian Springs, NV. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Two comments were received. One comment is in favor of the Class E airspace revocation and the other comment is opposed to the airspace revocation.

The commenter who opposes the Class E revocation discussed concerns about the airspace's future use. Class E airspace areas, extending upward from 700 feet or more above the surface of the earth, are designated for airports with approved instrument approach procedure. Creech AFB Airport does not have approved instrument approach procedures, as such, the Class E airspace is being revoked. If the airport develops instrument procedures, the FAA will reevaluate the airspace to ensure containment of the instrument procedures.

Class D and Class E5 airspace designations are published in paragraphs 5000, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 revokes the Class E airspace extending

upward from 700 feet above the surface at Creech AFB Airport, Indian Springs, NV. This type of Class E airspace is designed to contain instrument approach procedures. This Class E airspace area is not required because there are no instrument procedures published for Creech AFB Airport.

This action also implements two administrative updates to the Class D legal description. The second line of the text header is updated from “Indian Springs Air Force Auxiliary Field, NV” to “Creech AFB Airport, NV”, to match the FAA database. Additionally, the third line of the text header is updated from “(lat. 36°35’14” N, long. 115°40’24” W)” to “(lat. 36°35’11” N, long. 115°40’39” W)”, to match the FAA database.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP NV D Indian Springs, NV [Amended]

Creech AFB Airport, NV
(Lat. 36°35’11” N, long. 115°40’39” W)

That airspace extending upward from the surface to and including 5,700 feet MSL within a 5-mile radius of the airport, excluding Restricted Area R-4806W. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

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

* * * * *

AWP NV E5 Indian Springs, NV [Revoked]

Indian Springs Air Force Auxiliary Field, NV
(Lat. 36°35’14” N, long. 115°40’24” W)

Issued in Des Moines, Washington, on October 1, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–21933 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 232 and 239

[Release Nos. 33–10984; 34–93056; 39–2540; IC–34376]

Adoption of Updated EDGAR Filer Manual, Form ID Amendments

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (“Commission”) is adopting amendments to Volumes I and II of the Electronic Data Gathering, Analysis, and Retrieval system (“EDGAR”) Filer Manual (“Filer Manual”) and related rules and forms. The EDGAR system was upgraded on September 20, 2021.

DATES: *Effective date:* October 7, 2021. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of October 7, 2021.

FOR FURTHER INFORMATION CONTACT: For questions regarding the amendments to Volumes I and II of the Filer Manual and related rules, please contact Rosemary Filou, Deputy Director and Chief Counsel, or Daniel Chang, Senior Special Counsel, in the EDGAR Business Office at (202) 551–3900. For questions concerning the updates to Forms 24F–2, N–RN, N–CEN, or N–PORT, please contact Heather Fernandez in the Division of Investment Management at (202) 551–6708. For questions concerning the changes to Form X–17A–5, please contact Rose Wells, Senior Counsel, in the Division of Trading and Markets at (202) 551–5527. For questions concerning submission form types SBS DISPUTE NOTICE and SBS DISPUTE NOTICE/A, please contact Andrew Bernstein, Senior Special Counsel, in the Division of Trading and Markets at (202) 551–5565. For questions regarding the changes to submission form types D, D/A, or 424I, please contact Chris Windsor, Senior Special Counsel, in the Division of Corporation Finance at (202) 551–3419. For questions concerning the taxonomies or schemas, please contact the Office of Structured Disclosure in the Division of Economic and Risk Analysis at (202) 551–5494.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, Volume I: “General Information,” Version 39 (September 2021) and Volume II: “EDGAR Filing,” Version 59 (September 2021), amendments to 17 CFR 232.301 (“Rule 301 of Regulation S–T”); and amendments to Form ID (referenced in 17 CFR 239.63, 17 CFR 269.7, and 17 CFR 274.402). The updated Filer Manual volumes are incorporated by reference into the Code of Federal Regulations.

I. Background

The Filer Manual contains technical specifications needed for filers to make submissions on EDGAR. Filers must comply with the applicable provisions of the Filer Manual in order to assure

the timely acceptance and processing of filings made in electronic format.¹ Filers should consult the Filer Manual in conjunction with our rules governing mandated electronic filings when preparing documents for electronic submission.

II. Amendments to Volume I of the Filer Manual and Form ID

Volume I of the EDGAR Filer Manual provides that new filers must request EDGAR access by submitting Form ID.² Form ID will be revised to include a privacy notice that will supplement the general Privacy Act Notice available at *SEC.gov* by providing more detailed information tailored to Form ID.³

Form ID will also be revised to clarify that information provided on the form may become publicly available. Form ID requires new filers to provide mailing, business, and contact addresses; telephone numbers for those addresses; and their email address. It is not uncommon for individual filers or small business owners to list personal telephone numbers and home addresses on Form ID. Although Form ID submissions are not publicly posted, some information from Form ID is made public and some information may be automatically incorporated in other filings.⁴

Separately, Volume I will be amended to alert filers that the staff may request that filers provide relevant documents to support requests to change a company name. Currently, Volume I requires that filers maintain current company information in EDGAR. Changes to a filer's company name are manually reviewed by SEC staff. Requesting that filers provide documents supporting name changes will further the integrity of EDGAR by helping assure that company names on accounts are accurate.

¹ See Rule 301 of Regulation S-T.

² Form ID, uniform application for access codes to file on EDGAR (referenced in 17 CFR 239.63, 249.446, 269.7, and 274.402). Form ID requests limited identity information regarding the applicant, e.g., name, address and telephone number.

³ See the SEC's Privacy Act Notice available at www.sec.gov/privacy.htm. Among other things, the privacy notice in Form ID will include the authority that authorizes the solicitation of information, the principal purpose for which the information is to be used, the routine uses which may be made of the information, and the effects of not providing the requested information.

⁴ In particular, the filer's mailing and business addresses are generally posted on EDGAR as header information for most filings.

III. EDGAR System Changes and Associated Modifications to Volume II of the EDGAR Filer Manual

EDGAR is being updated in Release 21.3, and corresponding amendments to Volume II of the Filer Manual will be made to reflect these changes, as described below.⁵

On April 8, 2020, the Commission adopted rules to modify the registration, communications, and offering processes for business development companies ("BDCs") and other closed-end investment companies under the Securities Act of 1933.⁶ As part of the rulemaking, the Commission amended 17 CFR 230.424, 230.456, and 230.457 (Securities Act rules 424, 456, and 457), as well as Forms S-1, S-3, F-1, and F-3 to permit issuers of certain continuously offered, exchange-traded products that share a number of similarities to exchange-traded funds, but are not registered under the Investment Company Act, to elect to register an offering of an indeterminate amount of securities and to pay registration fees in a manner consistent with mutual funds and exchange-traded funds. Accordingly, EDGAR Release 21.3 will add new submission form type 424I to permit these filers to register an offering of "Exchange-Traded Vehicle Securities," with registration fees due annually on a net basis.

As part of that same rulemaking, the Commission adopted a requirement that filings on Form 24F-2 be submitted in a structured format. EDGAR Release 21.3 will introduce a Pilot phase for filing Form 24F-2 in a structured format.

On November 2, 2020, the Commission adopted a new rule and amended an existing rule and forms to provide an updated, comprehensive approach to the regulation and use of derivatives and certain other transactions by mutual funds (other than money market funds), exchange-traded funds, registered closed-end funds, and BDCs (collectively "funds").⁷ To implement these changes, EDGAR Release 21.3 will add new submission form types N-RN and N-RN/A (formerly known as N-LIQUID and N-LIQUID/A) to allow funds to report certain information confidentially to the Commission. EDGAR Release 21.3 will

⁵ EDGAR Release 21.3 will be deployed on or about September 20, 2021. EDGAR Release 21.2 was deployed on June 21, 2021.

⁶ See Securities Offering Reform for Closed-End Investment Companies, Release 33-10771 (Apr. 8, 2020) [85 FR 33290 (June 1, 2020)].

⁷ See Use of Derivatives by Registered Investment Companies and Business Development Companies, Release No. IC-34084 (Nov. 2, 2020) [85 FR 83162 (Dec. 21, 2020)].

also revise submission form types N-CEN, N-CEN/A, NPORT-P, NPORT-P/A, NPORT-NP, and NPORT-NP/A to allow funds to report certain information regarding derivatives and other transactions.

On September 19, 2019, the Commission adopted recordkeeping, reporting, and notification requirements applicable to security-based swap dealers ("SBSDs") and major security-based swap participants ("MSBSPs"), securities count requirements applicable to certain SBSDs, and additional recordkeeping requirements applicable to broker-dealers to account for their security-based swap and swap activities.⁸ Accordingly, EDGAR Release 21.3 will update EDGAR to allow reports on Form X-17A-5 to be filed by two new categories of registrants (SBSDs and MSBSPs).

On December 18, 2019, the Commission adopted rules requiring the application of specific risk mitigation techniques to portfolios of uncleared security-based swaps.⁹ To implement one of these rules, which relates to the requirement to reconcile outstanding securities-based swap transactions, EDGAR Release 21.3 will add new submission form types SBS DISPUTE NOTICE and SBS DISPUTE NOTICE/A to allow SBSDs and MSBSPs to provide the Commission with notices of certain valuation disputes with their counterparties.

On November 2, 2020, the Commission amended rules and forms to simplify, harmonize, and improve certain aspects of the exempt offering framework to promote capital formation while preserving or enhancing important investor protections.¹⁰ To implement these rules, EDGAR Release 21.3 will increase the Total Offering Amount in "Item 13: Offering and Sales Amounts" from a maximum of \$5 million to \$10 million if any "Rule 504" (17 CFR 230.504) item is selected on submission form types D and D/A.

Also, the following updates will be made to Volume II of EDGAR Filer Manual:

- EDGAR will no longer accept the IFRS-2019 Taxonomy. Please see <https://www.sec.gov/info/edgar/>

⁸ See Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers, Release No. 34-87005 (Sept. 19, 2019) [84 FR 68550 (Dec. 16, 2019)].

⁹ See Risk Mitigation Techniques for Uncleared Security-Based Swaps, Release No. 34-87782 (Dec. 18, 2019) [85 FR 6359 (Feb. 2, 2020)].

¹⁰ See Facilitating Capital Formation and Expanding Investment Opportunities by Improving Access to Capital in Private Markets, Release No. 33-10884 (Nov. 2, 2020) [86 FR 3496 (Jan. 14, 2021)].

edgartaxonomies.shtml for a complete list of supported standard Taxonomies in EDGAR.¹¹

- EDGAR will no longer use the description “Taiwan, Province of China” for Taiwan and will only use the term “Taiwan” without a following modifier, in compliance with the U.S. Government’s Geopolitical Entities, Names, and Codes Standard. The state/country list of values for all XML Schemas will be updated to reflect this change.

- EDGAR will be updated to accept the SBSE-C Certification form immediately after receiving the SBSE registration forms SBSE, SBSE-A and SBSE-BD.

EDGAR Release 21.3 will also make general functional updates that do not require changes to the Filer Manual. In particular:

- The EDGAR Filer Management, EDGAR Filing, and EDGAR Online Forms Management websites will be updated to eliminate support for Internet Explorer and add support for Microsoft Edge, in accord with the SEC’s move to Edge generally.

- The three websites will also be revised to include a general privacy notice, similar to the more detailed privacy notice that will be included in Form ID discussed in Section II.¹² The general privacy notice will link to the Privacy Act Notice available at *SEC.gov* and to guidance for filers regarding how to remove personally identifiable information (PII) inadvertently included in EDGAR filings.¹³

IV. Amendments to Rule 301 of Regulation S-T

Along with the adoption of the updated Filer Manual, we are amending Rule 301 of Regulation S-T to provide for the incorporation by reference into the Code of Federal Regulations of the current revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual is available at <https://www.sec.gov/edgar/filer-information/current-edgar-filer-manual>. Typically, the EDGAR Filer Manual is also available for website viewing and printing in the

¹¹ Currently, taxonomies supported by EDGAR include USGAAP 2021, USGAAP 2020, SRT 2020, IFRS 2021, IFRS 2020, and IFRS 2019.

¹² See *supra* note 3 and accompanying text. These websites currently contain an EDGAR Privacy Notice, but that notice has been superseded by the SEC’s Privacy Act Notice available at www.sec.gov/privacy.htm.

¹³ See the SEC’s Privacy Act Notice available at www.sec.gov/privacy.htm; Correct, withdraw, or delete a filing available at https://www.sec.gov/edgar/filer-information/how-do-i-list_ref_3.

Commission’s Public Reference Room, 100 F Street NE, Room 1580, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission’s Public Reference Room.

V. Administrative Law Matters

Because the Filer Manual, and form and rule amendments, relate solely to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties, publication for notice and comment is not required under the Administrative Procedure Act (“APA”).¹⁴ It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act¹⁵ or a report to Congress under the Small Business Regulatory Fairness Act.¹⁶

The effective date for the updated Filer Manual and related rule amendments is October 7, 2021. In accordance with the APA,¹⁷ we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the related system upgrades.

VI. Statutory Basis

We are adopting the amendments to Regulation S-T and Form ID under the authority in Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,¹⁸ Sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,¹⁹ Section 319 of the Trust Indenture Act of 1939,²⁰ and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.²¹

List of Subjects

17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

17 CFR Part 239

Reporting and recordkeeping requirements, Securities.

¹⁴ 5 U.S.C. 553(b)(A).

¹⁵ 5 U.S.C. 601 through 612.

¹⁶ 5 U.S.C. 804(3)(C).

¹⁷ 5 U.S.C. 553(d)(3).

¹⁸ 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

¹⁹ 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78o-4, 78w, and 78ll.

²⁰ 15 U.S.C. 77sss.

²¹ 15 U.S.C. 80a-8, 80a-29, 80a-30, and 80a-37.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S-T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z-3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a-6(c), 80a-8, 80a-29, 80a-30, 80a-37, 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: “General Information,” Version 39 (September 2021). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 59 (September 2021). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available at <https://www.sec.gov/edgar/filer-information/current-edgar-filer-manual>. Typically, the EDGAR Filer Manual is also 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 a.m. and 3 p.m. Operating conditions may limit access to the Commission’s Public Reference Room. You can also inspect the document 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>.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 3. The general authority citation for part 239 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78o–7 note, 78u–5, 78w(a), 78ll, 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37; and sec. 107, Pub. L. 112–106, 126 Stat. 312, unless otherwise noted.

* * * * *

■ 4. Form ID (referenced in §§ 239.63, 249.446, 269.7, and 274.402) is amended by revising the page titled “General Instructions” to read as follows:

Note: The text of Form ID does not, and the amendments will not, appear in the Code of Federal Regulations.

Form ID

Uniform Application for Access Codes to File on EDGAR

* * * * *

General Instructions

* * * * *

Privacy Act Statement

Authorities: The information is sought pursuant to 15 U.S.C. 77a *et seq.*, 15 U.S.C. 77aaa *et seq.*, 78a *et seq.*, 80a–1 *et seq.*, and 17 CFR 232.10.

Purpose: The information solicited on this form will be used to determine whether to allow applicants to make filings on EDGAR, and, where access is granted, to establish and maintain the filer’s EDGAR account.

Routine Uses: Uses for the information collected can be found in the System of Records Notice SEC–33: General Information Technology Records. See https://www.sec.gov/about/privacy/sorn/sec-33_sec_general_information_technology_records.pdf.

Disclosure: Providing this information is voluntary. Failure to provide the information requested on this form, however, may affect the determination whether to allow applicants to make filings on EDGAR.

Please note that information submitted on Form ID may become public.

* * * * *

By the Commission.

Dated: September 20, 2021.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2021–21915 Filed 10–6–21; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 11458]

RIN 1400–AE82

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act; Validity of Visa

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule replaces an outdated form name and number with a revised form name and number used for processing exchange visitor visas and updates the agency responsible for maintaining the form.

DATES: This final rule is effective November 8, 2021.

FOR FURTHER INFORMATION CONTACT:

Andrea B. Lage, Acting Regulatory Coordinator, U.S. Department of State, Bureau of Consular Affairs, Visa Services, 600 19th Street NW, Washington, DC 20522, 202–485–7586, VisaRegs@state.gov.

SUPPLEMENTARY INFORMATION: This rule makes a technical update to replace an outdated reference to Form IAP–66, Certificate of Eligibility for Exchange Visitor Status, with the updated name of Form DS–2019, Certificate of Eligibility for Exchange Visitor Status (J–NONIMMIGRANT) (hereinafter, Form DS–2019), which the Department of State has maintained since 2001.

Effective October 1, 1999, in accordance with sections 301 and 312 of the Foreign Affairs Reform and Restructuring Act of 1998, as amended,¹ the United States Information Agency, which administered the Exchange Visitor Program, was abolished and its functions were transferred to the Department of State. Following the transfer, the Department of State’s Bureau of Educational and Cultural Affairs (ECA) assumed responsibility for the Exchange Visitor Program. On October 11, 2001, the Office of Management and Budget approved ECA’s request to replace the Form IAP–66 with Form DS–2019. Then, on April 11, 2002, ECA published an interim final rule that replaced the outdated Form IAP–66 with the new Form DS–2019 in several sections of 22 CFR part 62,² but no corresponding changes were made in 22 CFR part 41 at the time.

Exchange Visitor Program sponsors issue Forms DS–2019 to prospective exchange visitors. The Form DS–2019 identifies the exchange visitor and his

or her designated sponsor, and provides a brief description of the exchange visitor’s program, including the start and end date, category of exchange, and an estimate of the cost of the exchange program. The prospective exchange visitor must provide a properly executed Form DS–2019 to a consular officer to be issued a J–1 nonimmigrant visa. See 22 CFR 41.62(a)(1). After being admitted to the United States, a responsible officer extending the program of an exchange visitor is required to provide the exchange visitor a duly executed Form DS–2019 reflecting the extension and provide a notification copy of such form to the Department of State. 22 CFR 62.43(b).

By amending 22 CFR 41.112, this rule will update the Department’s regulations governing the process through which the validity of an expired nonimmigrant visa may be automatically extended to the date of application for readmission under certain circumstances. Certain exchange visitors may apply with DHS for readmission after an absence of 30 days or less solely in a contiguous territory or adjacent islands other than Cuba by presenting a current Form DS–2019 and a valid passport.³ 22 CFR 41.112(d)(2)(ii). Additionally, in cases where DHS has changed the original nonimmigrant classification to another nonimmigrant classification, the validity of the expired or unexpired nonimmigrant visa may be considered to be automatically extended to the date of application for admission, and the visa may be converted as necessary to that changed classification. 22 CFR 41.112(d)(1)(ii).

Regulatory Findings

Administrative Procedure Act

This rule constitutes a rule of policy and procedure, and as a result, it is exempt from notice and comment under 5 U.S.C. 553(b)(3)(A).

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553(b), it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory

³ To be eligible to seek admission based on automatic extension of nonimmigrant visa validity, the applicant must have maintained and intend to resume nonimmigrant status; be applying for readmission within the authorized period of initial admission or extension of stay; not require authorization for admission under section 212(d)(3) of the Immigration and Nationality Act, 8 U.S.C. 1182(d)(3); not have applied for a new visa while abroad; and not be a national of a country identified as supporting terrorism in the Department’s annual Patterns of Global Terrorism report.

¹ 22 U.S.C. 6501.

² 67 FR 17613 (April 11, 2002).

Flexibility Act (5 U.S.C. 601 *et seq.*). Nonetheless, the Department of State certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule does not require the Department of State to prepare a statement because it will not result in any such expenditure, nor will it significantly or uniquely affect small governments. This rule involves visas, which involves foreign individuals, and does not directly or substantially affect state, local, or tribal governments, or businesses.

Congressional Review Act

This rule is not a major rule as defined in 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

Executive Orders 12866 and 13563

Executive Orders 13563 and 12866 direct agencies to assess 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, distributed impacts, and equity). These Executive Orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Department of State has examined this rule in light of Executive Order 13563, and has determined that the rulemaking is consistent with the guidance therein. The Department of State has reviewed this rulemaking to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866. There are no anticipated direct costs to the public associated with this rule.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effect on the States, on the relationship between the national

government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders 12372 and 13132.

Executive Order 12988: Civil Justice Reform

The Department of State has reviewed the rule in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Section 5 of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35. The Form DS-2019, Certificate of Eligibility for Exchange Visitor Status (J-NONIMMIGRANT), is approved under the PRA (OMB Control No. 1405-0119).

List of Subjects in 22 CFR Part 41

Aliens, Cultural Exchange Program, Nonimmigrant, Visas.

Accordingly, for the reasons set forth in the preamble, 22 CFR Ppart 41 is amended to read as follows:

PART 41—VISAS: DOCUMENTATION OF NONIMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

- 1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1101; 1102; 1104; 1182; 1184; 1185 note (section 7209 of Pub. L. 108-458, as amended by section 546 of Pub. L. 109-295); 1323; 1361; 2651a.

- 2. In § 41.112, revise paragraph (d)(2)(i) to read as follows:

§ 41.112 Validity of visa.

* * * * *

(d) * * *

(2) * * *

(i) Is in possession of a Form I-94, Arrival-Departure Record, endorsed by DHS to show an unexpired period of

initial admission or extension of stay, *provided that* in the case of a qualified F student or the accompanying spouse or child of such student, is in possession of a current Form I-20, Certificate of Eligibility for Nonimmigrant Student Status, issued by the school that the student has been authorized to attend by DHS and endorsed by the issuing school official to indicate the period of initial admission or extension of stay authorized by DHS, and *provided that* in the case of a qualified J exchange visitor or the accompanying spouse or child of such exchange visitor, is in possession of a current Form DS-2019, Certificate of Eligibility for Exchange Visitor Status (J-NONIMMIGRANT), issued and endorsed by the Department of State-designated sponsor of the exchange program, to indicate the period of initial admission authorized by DHS or the extension of stay authorized by the Department of State;

* * * * *

Kevin E. Bryant,

Deputy Director, Office of Directives Management, Department of State.

[FR Doc. 2021-21249 Filed 10-6-21; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 247, 880, 882, 884, 966

[Docket No. FR-6286-I-01]

RIN 2501-AD99

Extension of Time and Required Disclosures for Notification of Nonpayment of Rent

AGENCY: Office of the Assistant Secretary of Public and Indian Housing, and Office of the Assistant Secretary for Housing-Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Interim final rule.

SUMMARY: This interim final rule applies when, during emergencies such the current COVID-19 pandemic, Federal funding is available to assist tenants with nonpayment of rent and tenants facing eviction for nonpayment of rent in public housing and properties with project-based rental assistance (PBRA) (for purposes of this rule, PBRA includes projects in the following programs: Section 8, Section 8 Moderate Rehabilitation, Section 202/162 Project Assistance Contract, Section 202 Project Rental Assistance Contract (PRAC), Section 811 PRAC, Section 236 Rental

Housing Assistance Program and Rent Supplement) need sufficient time and information to seek and receive such emergency rent relief. This interim final rule will allow the Secretary, upon making the requisite findings and providing the requisite notice, to require housing providers participating in those programs to provide tenants facing eviction for non-payment of rent with notification of and information about the opportunity to secure emergency funding and additional time to secure such funding prior to eviction.

DATES:

Effective date: November 8, 2021.

Comment due date: November 8, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this interim final rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410-0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail.

Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410-0500.

2. Electronic Submission of

Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at www.regulations.gov. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the www.regulations.gov website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications

submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202-402-3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Information Relay Service, toll-free, at 800-877-8339. Copies of all comments submitted are available for inspection and downloading at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: For Public and Indian Housing: Danielle Bastarache, Deputy Assistant Secretary for Public Housing and Voucher Programs, 451 7th Street SW, Room 4204, Washington, DC 20410, telephone number 202-402-1380 (this is not a toll-free number). For a quicker response, email PIH-COVID@hud.gov. For Multifamily: Robert Iber, Senior Advisor for the Office of Multifamily Housing Programs, 451 7th Street SW, Room 6106, Washington, DC 20410, telephone number 202-708-3055 (this is not a toll-free number). For a quicker response, email mfcommunications@hud.gov. Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Relay Service at 800-877-8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: This rule provides that, during the COVID-19 pandemic and other future emergencies, the Secretary may require that public housing authorities (PHAs) and PBRA owners provide tenants with specified information regarding any Federal funding that is made available to prevent eviction for nonpayment of rent during such emergency. The Secretary may also extend the time period before lease termination for nonpayment of rent to a minimum of 30 days after the tenant has received such information. This interim final rule will provide an important opportunity for tenants who face hardship due to emergencies, such as those who have lost income during the COVID-19 pandemic and are unable to pay rent, to learn about emergency funding opportunities and take steps to secure emergency funding. This will in turn prevent unnecessary evictions that would negatively impact the efficacy of HUD's programs.

I. Background

Since the first case of coronavirus disease 2019 (COVID-19) was discovered in the United States in

January 2020, the disease has infected over 40 million Americans and killed over 631,000.¹ The disease significantly impacted the economy, resulting in millions of Americans losing their jobs or working fewer hours. In April 2020, the national unemployment rate reached its highest level in over seventy years following the most severe month-over-month decline in employment on record.² Between March 15 and May 15, 2020, over 35 million Americans filed initial jobless claims, and the unemployment rate climbed to over 14 percent in April 2020—the highest monthly level since 1948, when the U.S. Bureau of Labor Statistics started tracking this data.³ The loss of jobs created by the COVID-19 pandemic exacerbated an affordable housing crisis that predated the pandemic. During this time, many households have faced housing insecurity.⁴ Amid this once-in-a-century crisis, HUD and the Federal Government began intense efforts to provide support for affected families, and State, territorial, Tribal, and local governments (State, local, and Tribal governments) have been called on to respond to this crisis with emergency assistance at an immense scale.

On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a determination under section 319 of the Public Health Service Act,⁵ that a national public health emergency existed as of January 27, 2020, because of the COVID-19 pandemic.⁶ On March

¹ Centers for Disease Control and Prevention (CDC), *COVID Data Tracker*, <http://www.covid.cdc.gov/covid-data-tracker/#datatracker-home> (last visited Sept. 9, 2021).

² Federal Reserve Bank of St. Louis, *Unemployment Rate [UNRATE]*, <https://fred.stlouisfed.org/series/UNRATE> (last visited Sept. 9, 2021); Federal Reserve Bank of St. Louis, *Employment Level [LNU02000000]*, <https://fred.stlouisfed.org/series/LNU02000000> (last visited Sept. 9, 2021).

³ U.S. Department of Labor, *Unemployment Insurance Weekly Claims Report*, May 21, 2020, <https://www.dol.gov/sites/dolgov/files/OPA/newsreleases/ui-claims/20201058.pdf>.

⁴ Nirmita Panchal et al., *The Implications of COVID-19 for Mental Health and Substance Abuse*, Feb. 10, 2021, <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>; U.S. Census Bureau, *Household Pulse Survey Data Tables*, <https://www.census.gov/programs-surveys/household-pulse-survey/datasets.html> (last visited Sep. 9, 2021); Rebecca T. Leeb et al., *Mental Health-Related Emergency Department Visits Among Children Aged <18 Years During the COVID Pandemic—US, Jan. 1–Oct. 17, 2020*, *Morb. Mortal. Wkly. Rep.* 69(45):1675–80 (Nov. 13, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6945a3.htm>.

⁵ 42 U.S.C. 247d.

⁶ The HHS Secretary renewed this determination several times since then, most recently on July 19, 2021 (effective July 20, 2021). HHS, *Renewal of Determination That A Public Health Emergency Exists*, July 19, 2021, <https://www.phe.gov/>

13, 2020, the President declared a nationwide emergency pursuant to Section 501(b) of the Stafford Act.⁷ All 50 states, the District of Columbia, and 5 territories were approved for major disaster declarations to assist with additional needs identified under the nationwide emergency declaration for COVID-19. On February 21, 2021, the President extended the national emergency, stating that the COVID-19 pandemic remains a significant risk to the United States.⁸

Response to the COVID-19 Pandemic and Related Housing Insecurity

In response to the national emergency declaration, HUD and other Federal agencies began efforts to support families impacted financially by the COVID-19 pandemic and at risk of losing their housing.⁹ Additionally, the Coronavirus Aid, Relief, and Economic Security Act, 2020 “CARES Act,” a \$2.2 trillion economic stimulus bill, was signed into law on March 27, 2020.¹⁰ Included in the CARES Act were provisions providing foreclosure and eviction moratoriums and providing additional financial relief for owners of certain multifamily housing projects in an effort to ensure continued stability of the housing market.¹¹

Also included in the CARES Act was funding for several HUD programs to prevent, prepare for, and respond to COVID-19, including increased rental subsidies in HUD-assisted housing to pay for increased operating costs and loss of rental income due to tenants’ loss of income during the COVID-19 national emergency. This additional funding was meant to help ensure that HUD’s assisted housing programs continued to operate as effectively as possible and were not burdened by the additional expenses associated with preventable evictions.

Other efforts were also underway to prevent an onslaught of evictions that

would lead to an increase in homelessness and cohabitation, which according to the CDC, also create an environment that would further spread COVID-19.¹² As a result, on September 4, 2020, the CDC Director issued an Order temporarily halting evictions in the United States due to the ongoing public health crisis.¹³ That original CDC Order expired on December 31, 2020, subject to extension, modification, or rescission. The Consolidated Appropriations Act, 2021,¹⁴ extended that Order until January 31, 2021, and the original CDC Order was extended multiple times due to the continued national emergency.

On August 3, 2021, following the surge in COVID-19 infections due to the highly contagious Delta variant, the CDC Director issued a new order temporarily halting evictions for persons in jurisdictions experiencing substantial or high rates of transmission. However, on August 26, 2021, the Supreme Court of the United States vacated the stay of a district court decision invalidating the original and new CDC Order, holding that the applicants had a substantial likelihood of success on the merits.¹⁵ In considering the facts, the Court pointed to the availability of rental-assistance funds as, in its view, diminishing the government’s ongoing interest in maintaining an eviction moratorium.¹⁶ Therefore, without the CDC Order in place, landlords may resume evictions across the United States during the national emergency, unless otherwise precluded under state or local eviction moratoriums.

Emergency Rental Assistance

In addition to trying to reduce evictions through the CARES Act, Congress created the Emergency Rental Assistance (ERA) program, funded through the Department of the Treasury, to make funds available to assist households that are unable to pay rent or utilities and provide funds to landlords to help cover tenants’ rent and utilities payments.

The first tranche of ERA funding, ERA1, provides up to \$25 billion under the Consolidated Appropriations Act,

2021, and the second tranche, ERA2, provides up to \$21.55 billion under the American Rescue Plan Act of 2021, which was enacted on March 11, 2021.¹⁷ The funds are provided directly to states, U.S. territories, local governments, and, in the case of ERA1, also to Indian tribes or Tribally Designated Housing Entities, as applicable, and the Department of Hawaiian Home Lands. Grantees then make these funds available to provide rental assistance to eligible households through existing or newly created rental assistance programs. These funds may be disbursed to either tenants or landlords. Public Housing Authorities (PHAs), Housing Choice Voucher (HCV) landlords, other owners of HUD-assisted properties, and utility providers may accept funds from the ERA program for rental and most utility arrearages for HUD-assisted families. HUD-assisted families are eligible for assistance from the ERA program, provided that ERA funds are not applied to costs that have been or will be reimbursed under any other Federal assistance, including Housing Assistance Payments in the HCV Program, Operating Fund assistance in the Public Housing program, or rental assistance in Multifamily Housing programs.

The funding is designed to assist households that demonstrate a risk of experiencing homelessness or housing instability. Eligible households for ERA must have a household income at or below 80 percent of area median income, which corresponds with income thresholds for HUD assistance.¹⁸ For both ERA1 and ERA2, other expenses related to housing include relocation expenses (including prospective relocation expenses), such as rental security deposits, and rental fees, which may include application or screening fees. Those expenses can also include reasonable accrued late fees (if not included in rental or utility arrears), and internet service provided to the rental unit.

The pace of distributing emergency funds that could prevent evictions for nonpayment of rent started slowly and faces a number of obstacles but has since picked up. From January to May 2021, only \$1.45 billion was delivered under ERA for rent, utilities, and arrears out of a total of \$25 billion.¹⁹ In June

[emergency/news/healthactions/phe/Pages/COVID-19July2021.aspx](https://www.emergency/news/healthactions/phe/Pages/COVID-19July2021.aspx).

⁷ 42 U.S.C. 5121 *et seq.*

⁸ See The White House, *A Letter on the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic*, Feb. 24, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/a-letter-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic/>.

⁹ See, e.g., HUD, *Mortgage Letter 2020-04: Foreclosure and Eviction Moratorium in Connection with the Presidentially Declared COVID-19 National Emergency*, Mar. 18, 2020, <https://www.hud.gov/sites/dfiles/OCHCO/documents/20-04hsgml.pdf>; U.S. Dep’t of Agriculture, *Stakeholder Announcement: USDA Announces Guaranteed Housing Foreclosure and Eviction Relief*, Mar. 19, 2020, <https://www.rd.usda.gov/node/17107>.

¹⁰ Public Law 116-136, 134 Stat. 281 (2020).

¹¹ *Id.* at sections 4022-4024.

¹² 86 FR 34013 (The 2017 Census Bureau American Housing Survey found that 32% of renters reported that they would move in with friends or family members upon an eviction.)

¹³ 85 FR 55292 (pursuant to the CDC’s authority under the Public Health Service Act, 42 U.S.C. 264).

¹⁴ Public Law 116-260 (2020).

¹⁵ *Ala. Ass’n of Realtors v. Dep’t of Health and Human Servs.*, 594 U.S. ___ (2021) at 5, https://www.supremecourt.gov/opinions/20pdf/21a23_ap6c.pdf.

¹⁶ *Id.* at 7-8 (“Whatever interest the Government had in maintaining the moratorium’s original end date to ensure the orderly administration of those programs has since diminished.”).

¹⁷ Public Law 117-2 (2021).

¹⁸ Emergency Rental Assistance limits eligibility to households with income that does not exceed 80 percent of the median income for the area in which the household is located, as determined by HUD. Public Law 116-260, division N, section 501 (2020).

¹⁹ Congressional Research Service, *Emergency Rental Assistance through the Coronavirus Relief*

2021, more than \$1.5 billion from ERA was paid directly to households, more than in all previous months combined.²⁰ July 2021 data demonstrates continued, steady improvement in funds distribution, particularly by States and local agencies following the Department of Treasury guidance.²¹

The application and approval process for ERA funds and the time it takes to access these funds vary by grantee. While it may generally be expected to take a few weeks for applications to be processed, and funds to be disbursed, some applicants have faced longer delays.²²

There are multiple causes for the slow rollout of ERA assistance. Of particular concern with respect to this rulemaking, they include obstacles to tenants knowing about and applying for available funds, such as complexities in the application processes, privacy concerns, and a lack of understanding as to funding availability.²³ The bottom line is that ERA funding still has not reached many eligible tenants at risk of eviction for nonpayment, creating an increased risk that evictions will occur simply because funding that is specifically meant to help pay much or all of the back rent in question is not secured in time.

II. This Interim Final Rule

Tenants' Need for Greater Information and Time

HUD is continuously evaluating how best to help tenants and housing providers mitigate the pandemic's impact and economic issues arising during this national emergency, while ensuring that the various resources that are available to address the backlog of

unpaid rent are fully utilized. HUD has determined that, in the immediate aftermath of the judicial vacatur of the CDC eviction moratorium, it needs to act to prevent a wave of preventable evictions that will interfere with the orderly operation of HUD's programs and the accomplishment of HUD's mission. Historically, 3.6 million eviction cases are filed per year in the United States, resulting in 1.5 million annual eviction judgments.²⁴ But now, as more renters fell behind on their rental payments during the COVID-19 pandemic, many more households are at risk of eviction. As of July 2021, just before the CDC moratorium on evictions was vacated, 6.5 million households nationwide were at risk of eviction.

This interim final rule follows and complements earlier HUD actions, taken while the CDC moratoriums were in effect, aimed at assisting HUD-assisted tenants and landlords with securing available resources that assist with the payment of back rent and avoid unnecessary evictions for non-payment. For example, HUD issued guidance recommending that all PHAs make tenants aware of ERA funding and guidance about accepting ERA funding in multifamily housing.²⁵ Nonetheless, the ERA program's implementation indicates that many tenants (including in HUD-assisted properties) may remain unaware of or do not understand how to access ERA resources, have been unable to access the funds in time, or have incorrectly believed that they need not apply for ERA because rental obligations were suspended during the eviction moratorium. Many of those tenants may be eligible for ERA, yet they are not benefiting from it, thus requiring HUD to take this further, related action.²⁶

HUD also issued guidance requesting that PHAs and owners work with tenants to recertify their rents for loss income or job loss, thus effectively lowering the rent payment HUD-supported tenants must make and helping them avoid eviction. However,

the possibility of recertification does not replace access to ERA funding, for a variety of reasons. This policy has been helpful but has not fully solved the problem. Not every tenant who could benefit from recertification has, whether because PHAs and owners have not reached out offering recertifications or because the tenants have chosen for a variety of reasons not to seek recertification. Additionally, PHAs and owners might permit recertification for rent going forward, but not recertify the loss of income retroactively, meaning that coverage of rent arrears by ERA could still be necessary to help prevent future evictions.

HUD now must take further action to ensure that tenants in public housing and PBRA²⁷ assisted units who are eligible for funding during a national emergency are afforded notice about the funding and have the opportunity to secure it before a lease termination for nonpayment of rent occurs. Congress specifically intended that ERA funds would reduce what otherwise would be an intolerably high number of evictions due to financial issues caused by the national emergency. While States and localities continue to accelerate and improve their programs to provide funding to tenants, many tenants who now face imminent eviction with the moratorium gone still need additional time and information to access the ERA applications and complete the process. This interim final rule will ensure that HUD-assisted tenants who are facing eviction for nonpayment of rent have notice of available emergency funds and are afforded more time to access that assistance. A tenant who has been previously made aware of eligibility for emergency assistance may not think to apply for it until they are facing eviction, as many tenants now are following judicial vacatur of the CDC's eviction moratorium. HUD believes that getting tenants information about accessing emergency funding at the moment when they most need it and are likely to take advantage of it is crucial for fulfilling HUD's mission.

Statutory and Regulatory Authority

HUD has general rulemaking authority under 42 U.S.C. 3535 to implement its statutory mission, which

²⁷ HUD's PBRA programs included in the scope of this rule includes Section 8, Section 8 Moderate Rehabilitation, Section 202/162 Project Assistance Contract, Section 202 Project Rental Assistance Contract (PRAC), Section 811 PRAC, Section 236 Rental Housing Assistance Program and Rent Supplement. In addition, some housing developed with subsidized financing through former programs such as Section 221(d)(3) Below Market Interest Rate, Section 236 and Section 202 Direct Loan are part of HUD's PBRA Program.

Fund, (July 9, 2021) at 14, <https://crsreports.congress.gov/product/pdf/R/R46688>.

²⁰ U.S. Dep't of the Treasury, *Treasury Data: Amount of June Emergency Rental Assistance Resources to Households More Than All Previous Months Combined*, (July 21, 2021) <https://home.treasury.gov/news/press-releases/jy0284>.

²¹ U.S. Dep't of the Treasury, *Treasury Announces Seven Additional Policies to Encourage State and Local Governments to Expedite Emergency Rental Assistance*, (Aug. 25, 2021) <https://home.treasury.gov/news/press-releases/jy0333>.

²² U.S. Dep't of the Treasury, *Emergency Rental Assistance Data Shows Programs Ramping Up, but States and Localities Must Do More to Accelerate Aid*, (July 2, 2021) <https://home.treasury.gov/system/files/136/2021-07-02-ERA-Data-Blog-Post-vf.pdf>.

²³ See U.S. Dep't of the Treasury, *Emergency Rental Assistance Fact Sheet*, (May 7, 2021) https://home.treasury.gov/system/files/136/FACT_SHEET-Emergency-Rental-Assistance-Program_May2021.pdf; Nat'l Low Income Hous. Coal., *Treasury Emergency Rental Assistance Programs in 2021: Analysis of a National Survey*, (June 22, 2021) https://nlhcc.org/sites/default/files/HIP_NLIHC_Furman_2021_6-22_FINAL_v2.pdf.

²⁴ Ashley Gromis, *Eviction: Intersection of Poverty, Inequality, and Housing*, Princeton University, Eviction Lab (2019) (measuring the number of evictions from 2000 to 2016).

²⁵ HUD, *Questions on the U.S. Treasury's Emergency Rental Assistance (ERA) and Other Rental Assistance Programs*, May 12, 2021, https://www.hud.gov/sites/dfiles/PIH/documents/ERAP_PIH_ERAP_FAQs.pdf; HUD, *Questions and Answers for Office of Multifamily Housing Stakeholders, Coronavirus Disease 2019 (COVID-19)*, (July 29, 2021) https://www.hud.gov/sites/dfiles/Housing/documents/MF_COVID-19%20QA_7_29_21.pdf.

²⁶ Recent Census Pulse survey data shows that 60% of renter households behind on rent have not applied to ERA. See U.S. Census Bureau, *Household Pulse Survey Data Tables*, <https://www.census.gov/programs-surveys/household-pulse-survey/data.html> (last visited Sep. 9, 2021).

is to provide assistance for housing to promote “the general welfare and security of the Nation and the health and living standards of [its] people.”²⁸ Each year, HUD provides States, local governments, and housing providers with billions of dollars in Federal financial assistance, appropriated and authorized by Congress. By taking the actions described here, HUD will prevent unnecessary evictions and the costs associated with them for both tenants and PHAs and owners, as compelled by its mission. These actions will promote the general welfare and security of the Nation by avoiding the societal ills exacerbated by the dislocations wrought by evictions in the time of a national emergency, such as deterioration of public health through disease transmission, extended disruptions to children’s schooling after the prolonged period of disruption that many have already experienced during the current national emergency and all the other problems attendant to increased homelessness.

In addition, increases in evictions frustrates HUD’s programmatic efficiency. It diverts resources to cover the costs of unnecessary evictions. Increased homelessness also makes it more difficult for HUD to provide services to the population that qualifies for HUD’s programs. People experiencing homelessness are less likely to receive information about HUD’s programs and to avail themselves of those programs. Accordingly, by reducing evictions, this rulemaking advances HUD’s statutory purposes.

HUD also has specific statutory authority under the U.S. Housing Act of 1937 to prescribe procedures and requirements for PHAs to follow to ensure sound management practices and efficient operations.²⁹ Even more specifically, HUD has the authority to establish “procedures designed to assure the prompt payment and collection of rents and the prompt processing of evictions in the case of nonpayment of rent.”³⁰ HUD also has authority to specify procedures that ensure tenants receive the elements of due process, such as notice of relevant information, before adverse action is taken against them.³¹

In particular, the Secretary is authorized to require public housing authorities to provide certain specified notice periods and other procedural protections (that are, in turn, incorporated into lease terms) before

different types of eviction proceedings.³² In exercising that statutory authority, HUD’s regulations provide that in the case of termination for nonpayment of rent, a PHA shall provide at least fourteen days’ written notice. *See* 24 CFR 966.4.

The Secretary also has statutory authority to establish requirements for project-based rental assistance.³³ This statutory authority provides that during the lease term, the owner must not “terminate the tenancy except for serious or repeated violation of the terms and conditions of the lease, for violation of applicable Federal, State, or local law, or for other good cause[.]”³⁴ The Secretary is also authorized to provide additional terms and conditions that must be incorporated into the tenant’s lease.³⁵ This rulemaking is consistent with the statutory restrictions placed on program participants under this authority and HUD’s regulations promulgated in this area.

Specifically, for termination for nonpayment of rent in HUD’s project-based rental assistance programs, HUD’s regulations generally provide that a termination notice must be provided with enough advance time to comply with both the rental agreement or lease and State laws.³⁶ *See* 24 CFR 247.4(c); 24 CFR 880.607(c)(2). By contrast, for termination of tenancy for “other good cause,” HUD regulations require 30 days’ notice along with the provision of specific information to the tenant. *See* 24 CFR 880.607(c)(2). HUD imposes different notice requirements in specific programs; in one program, five working days’ notice are required before tenancy termination while in another program the regulations provide for 10 days. *See* 24 CFR 882.511; 24 CFR 884.216.

This interim final rule amends these program regulations for public housing and project-based rental assistance to accommodate current and future exigencies, based on HUD’s statutory authority and policy discretion, in three ways.

²⁸ 42 U.S.C. 1437d(l).

²⁹ 42 U.S.C. 1437f(g) (Section 8 low-income housing assistance); 12 U.S.C. 1701q (Section 202 supportive housing for the elderly); 42 U.S.C. 8013 (Section 811 supportive housing for persons with disabilities).

³⁰ 42 U.S.C. 1437f(d)(1)(B)(ii). *See also* 42 U.S.C. 8013(i)(2)(B) (Section 811).

³¹ 42 U.S.C. 1437f(d)(1)(B)(iv).

³² The time period required by State laws can vary from 0 days to 30 days depending on the jurisdiction. *See* Nolo, *State Laws on Termination for Nonpayment of Rent*, <https://www.nolo.com/legal-encyclopedia/state-laws-on-termination-for-nonpayment-of-rent.html> (last updated Dec. 10, 2020) (citing W.Va. Code Section 55–3A–1 (no notification period), Fla. Stat. Ann. Section 83.56(3) (3 days); Idaho Code Section 6–303(2) (3 days) and D.C. Code Ann. Section 42–3505.01 (30 days)).

First, it provides that, when funding is available to assist tenants with nonpayment of rent during a national emergency, such as the current COVID–19 pandemic, the Secretary may determine that tenants facing eviction for nonpayment of rent must be provided with adequate time and notice to secure that funding. Upon that determination, the PHA or owner seeking to evict for non-payment must provide the tenant with such information as required by the Secretary for accessing the funds that are being made available related to the emergency. HUD will publish a Notice outlining the specific information to be included in the lease termination notification to assist eligible tenants in obtaining funding during this emergency. The Notice will explain the requirements for PHAs and owners to provide the information in a manner that ensures effective communication for individuals with disabilities, such as by providing the information in accessible electronic formats or in Braille, and to provide meaningful access for persons with limited English proficiency (LEP).

Second, to ensure tenants facing eviction for non-payment of rent are provided an adequate opportunity to access emergency funding, this interim final rule also extends the lease termination time period for such tenants to at least 30 days following the above-described notification. This 30-day period is consistent with the longest of the standard periods to which PHAs and owners are already accustomed for many evictions. For example, for evictions for reasons other than nonpayment of rent, health or safety concerns, or criminal activity, 42 U.S.C. 1437d(l) and 24 CFR 966.4(l)(3) already provide for a 30-day time period, unless State or local law allows a shorter period.

Similarly, HUD’s PBRA regulations at 24 CFR 247.4, 24 CFR 880.607, and 24 CFR 882.511, as well as 42 U.S.C. 8013(i)(2)(B), all provide that when termination of the tenancy is based on other good cause, the tenancy will not terminate earlier than 30 days after the tenant receives the notice. Further, some state laws already provide for 30 days more generally or specifically for the current national emergency.³⁷

Third, the interim final rule provides that, for public housing, in addition to requiring the provision of specified information to tenants facing eviction

³⁷ *See, e.g.*, Colo. Executive Order No. D 2021–122, (July 8, 2021) <https://www.colorado.gov/governor/sites/default/files/inline-files/D%202021%20122.pdf>.

²⁸ 42 U.S.C. 3531.

²⁹ 42 U.S.C. 1437d(c)(4).

³⁰ 42 U.S.C. 1437d(c)(4)(B).

³¹ 42 U.S.C. 1437d(k).

for failure to pay rent, the Secretary may also require that all tenants be provided immediate notice of the availability of emergency funding. This notice may be posted in a public area, emailed to all tenants, or otherwise provided to groups of tenants rather than individuals, if the PHA so chooses.

HUD has chosen, based on its statutory authority for the public housing and PBRA programs,³⁸ its rulemaking authority,³⁹ and its policy discretion, to protect its assisted tenants and ensure it is fulfilling its statutory duties by promulgating this interim final rule.

HUD notes that this rule does not require PHAs or owners to modify tenant leases, which provide notification procedures and time periods that may be more limited than those provided in this rule. It would be administratively infeasible to update all public housing and PBRA leases to incorporate these changes, which are limited in the time they will be in effect, and to update all leases quickly enough to immediately protect families at-risk of eviction. However, the rule requires that PHAs and owners follow this rule in place of the usual lease provisions at times when its provisions are in effect, and does not prevent PHAs and owners from updating their leases if they so choose.

Administrative Procedure Act (APA)

In general, HUD publishes a rule for public comment before issuing a rule for effect, in accordance with both the APA, 5 U.S.C. 553, and its own regulations on rulemaking, 24 CFR part 10. Both the APA and Part 10, however, provide for exceptions from that general rule where HUD finds good cause to omit advance notice and public participation, in addition to the Secretary's statutory and regulatory authority to waive regulations.⁴⁰ The good cause requirement is satisfied when the prior public procedure is "impracticable, unnecessary, or contrary to the public interest."⁴¹ In order to publish a rule for effect prior to receiving and responding to public comments, the agency must make a finding that at least one of these "good cause" exceptions applies.

HUD has determined that good cause exists to promulgate this interim final rule without prior notice and comment, to ensure that tenants who are

imminently facing eviction for nonpayment of rent and are eligible for ERA funding receive the benefit of this rule's requirement of notice and an opportunity to access these funds. HUD finds that prior notice and comment is impracticable and would create undue harm by delaying this rule's effectiveness.

Given the recent vacatur of the CDC Order suspending evictions, which may put HUD-assisted tenants at risk of being abruptly evicted before they can receive ERA funding, immediate action is necessary to ensure that ERA funding reaches its intended beneficiaries quickly and efficiently. HUD is taking this action to foster stability in its own programs by preventing tenant turnover and increased homelessness; preventing unnecessary hardship for HUD-supported tenants; and promoting the most efficient and effective use of ERA funds.

HUD is also taking this action to prevent harm to HUD-assisted tenants and allow landlords and PHAs to avoid the time and expense of unnecessary evictions while simultaneously providing those landlords with the funds necessary to recoup arrearages and other eligible costs through ERA funding.

Good cause can be found when circumstances outside the agency's control make compliance with notice and comment impracticable.⁴² HUD's good-cause determination is based on, among other things, the following considerations.

First, delay to allow prior notice and comment would effectively moot a significant aspect of this rule. This interim final rule is urgently needed right now, because the CDC Moratorium was abruptly enjoined prior to its anticipated expiration and thus evictions for nonpayment of rent are likely to proceed imminently. As some State and local grantees are only in the beginning stages of distributing ERA funds, many tenants may be unaware of their eligibility for such assistance or may be waiting for distribution of such assistance rather than acting themselves. Housing providers giving tenants information about ERA funding as soon as possible, and providing them with time to apply for it before more evictions occur, is crucial to ensuring the program's success and realizing Congress's intent in providing for ERA funding in the first place. The change in this interim final rule must be

undertaken with expedience to ensure the maximum intended effects of ERA funding. Such potential harm to the public is increased right now, given the recent vacatur of the CDC order and the continued need for additional time for ERA funding to reach eligible beneficiaries, making it critical that this rule go into effect when it is needed most.

HUD's Regulatory Impact Analysis provides that an estimated 217,000 households could be protected under this rulemaking when implemented. Delaying this interim final rule's effective date for months would render it useless and unavailable for a significant fraction of the tenants and landlords who would benefit from the rule. That would result in unnecessary evictions, preventable homelessness, and increased cohabitation during a pandemic.

Second, aside from mooting this interim final rule's purpose, delay due to prior notice and comment would result in evictions that could have been prevented if tenants had received adequate notification that assistance was available, and the opportunity to apply for and receive approval and funding prior to being evicted. Specifically, during an advanced notice and comment period, it is likely that individuals who could have benefited from this rule would face eviction before the rule goes into effect. That includes tenants who are now in the process of applying for ERA; tenants who are eligible for ERA but do not know of their eligibility or how to apply; and those who have completed applications but are waiting for receipt of funds.

Third, increased evictions are harmful not only to the individual families who lose their housing, but to HUD's mission and society as a whole. This is particularly the case when the processing of unnecessary evictions leads to increased cost and administrative burden for program participants as well as an increase in homelessness and cohabitation in particularly vulnerable populations. As the Federal agency responsible for housing assistance and community development,⁴³ HUD has responsibility to promote housing stability and the efficient and effective use of its resources to secure housing for vulnerable families. An increase in evictions also leads to instability in communities from tenant turnover,⁴⁴

³⁸ 42 U.S.C. 1437d(l); 42 U.S.C. 1437f(g) (Section 8 low-income housing assistance); 12 U.S.C. 1701q (Section 202 supportive housing for the elderly); 42 U.S.C. 8013 (Section 811 supportive housing for persons with disabilities).

³⁹ 42 U.S.C. 3535.

⁴⁰ 42 U.S.C. 3535(q).

⁴¹ 5 U.S.C. 553(b)(B); 24 CFR 10.1.

⁴² 5 U.S.C. 553(b)(B); see, e.g., Tri-Cty. Tel. Ass'n v. FCC, 999 F.3d 714, 719–20 (D.C. Cir. 2021) (providing funds in an ongoing emergency caused by a natural disaster).

⁴³ 42 U.S.C. 3531.

⁴⁴ CB Richard Ellis (CBRE), *Apartment Turnover Declines Amid COVID-19 Crisis*, U.S. Multifamily Research Brief (June 2020) <https://www.cbre.us/>

children needing to change schools,⁴⁵ increased cohabitation,⁴⁶ and increased homelessness,⁴⁷ which harms owners and undercuts the effectiveness of HUD's work by increasing the strain on its resources and programs. Reducing evictions results in less costs and resources that PHAs and owners have to expend to process evictions; reduced costs associated with unit turnover; and reduction in burdens associated with bringing on new tenants. Additionally, there is potential benefit accruing to the landlord from the tenant's securing of ERA funding through the repayment of back rent using ERA funding. There is also benefit to PHAs and owners to maintain tenants who are otherwise good tenants other than the impact of the COVID-19 pandemic on their income.

Delaying the rulemaking for prior notice and comment would be impracticable and contrary to the public interest. HUD believes the public interest is best served by ensuring that all tenants can benefit from the opportunity to access ERA funding and stay in HUD-assisted housing than limiting such benefit only to tenants who would benefit from this rule after notice and comment.

HUD values public input in its rulemakings and believes that providing the opportunity for comment enhances its regulations. HUD's regulations on rulemaking at 24 CFR part 10, provide for 60-days of public comment for proposed rules and an exception for good cause. Additionally, HUD often solicits comments on its rules and provides for a 60-day comment period even when not required under the APA. Due to the COVID-19 national emergency, delaying this rule to accept

prior public comment would be contrary to the public interest. The provisions in this interim final rule are designed specifically to be limited in scope and apply only in a national emergency period. For the reasons explained above, HUD finds that there is good cause consistent with the public interest to issue the rule without advance notice and comment.

HUD's policy of providing 60 days for public comment only applies to proposed rules, not to interim final rules. In this case, HUD does not believe that 60 days is needed for public comment, given the limited changes being made in this interim final rule, and also believes it is in the public interest to secure comments quickly. In providing for 30-days, HUD anticipates reviewing any such comments on a rolling basis as they are received and acting quickly if it determines to adopt any suggestions that may be made in the public comments. For the reasons above, HUD has determined that in this case a 30-day public comment period is appropriate.

Other Justifications for the Interim Final Rule

In taking this action, HUD is protecting the efficient and effective operation of its public housing and project-based rental assistance programs, the interests of the tenants whose rent it subsidizes, and landlords' business needs. This interim final rule is narrowly tailored so that it will require, during an emergency such as this one, notification to be provided to tenants regarding the availability of emergency funds and a brief extension of the time that must be provided before lease termination for nonpayment of rent, thus permitting the tenant to seek to secure such emergency funds to cure the deficiencies before commencement of eviction. It will not change any other eviction procedures. This interim final rule does not require that PHAs or owners immediately amend leases in accordance with this rule, but it would not prohibit PHAs and owners from amending lease terms to be consistent with this rule if they so choose.

HUD recognizes that some housing providers are already supporting tenants' access to ERA funds and delaying evictions for nonpayment of rent. In fact, in HUD's rental assistance programs, households can recertify their income in the case of a job loss or other change in income so to avoid or reduce the likelihood of failure to pay rent delinquencies. Similarly, housing providers can also work with tenants to create repayment plans and to adjust rent amounts. HUD believes these to be

sound management practices that are aligned with this rule's purposes. However, not all housing providers may be providing additional time for tenants to access ERA funds, allowing recertifications to be retroactive to cover arrears, or actively encouraging tenants to recertify their income.

This focused interim final rule does not prevent evictions altogether, but instead requires PHAs and owners to provide information about accessing ERA and additional time to do so when there is an eviction for nonpayment of rent, thus minimizing costs associated with unit turnover from tenant to tenant, preventing unnecessary hardship for HUD-assisted tenants, and ensuring that housing providers can continue to operate effectively.

III. Alternatives Considered and Scope

This interim final rule's scope is limited to address only situations in which federally assisted public housing agencies and PBRA housing providers may access federally appropriated emergency funding to help tenants satisfy rent obligations caused by a national emergency, like the COVID-19 pandemic. It directly applies only in instances where tenants in certain HUD-supported housing are facing eviction due to nonpayment of rent during such an emergency and places the burden on HUD to provide the information necessary to include in the notice provided by PHAs and owners to tenants.

The interim final rule also seeks to balance the interest of tenants and the reliance of PHAs and multifamily owners in administering their program. The interim final rule provides for a modest period of additional time, 30-days, for tenants to apply for emergency financial assistance. HUD understands that some tenants may be unable to secure ERA funding, or future assistance provided to address an emergency, within a 30-day period. Administration of ERA assistance differs between states and localities and in some programs a PHA, owner, or tenant would not receive the ERA payment within 30-days of application. However, in considering what would be a reasonable and practical extension of time to *require*, HUD settled on 30 days because, as discussed above, it is a time-period to which owners are already accustomed, and it would have minimal impact on program operations. HUD also settled on at least 30 days because it is a set time frame for which PHAs and multifamily owners could rely for implementation.

HUD strongly encourages PHAs and owners to work with tenants who are

research-and-reports/US-Multifamily-Research-Brief--Apartment-Turnover-Dwindles-in-COVID-19-Crisis-June-2020.

⁴⁵ U.S. Centers for Disease Control and Prevention, *COVID-19 pandemic: Helping young children and parents transition back to school*, U.S. Centers for Disease Control and Prevention (Sept. 2, 2021) <https://www.cdc.gov/childrensmentalhealth/features/COVID-19-helping-children-transition-back-to-school.html>.

⁴⁶ See, e.g., L.E. D'Onofrio, Jr., F.D. Buono, and M.A.R. Coopera, *Cohabitation COVID-19 transmission rates in a United States suburban community: A retrospective study of familial infections*, U.S. National Library of Medicine, National Institutes of Health, (Jan. 16, 2021) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7816609/> ("The cohabitation infection attack rate of SARS-CoV-2 is significantly higher than previously reported. Age of household contacts and spousal relationship to the index case are risk factors for transmission of SARS-CoV-2 within a household.").

⁴⁷ Robert Collinson and Davin Reed, *The Effects of Evictions on Low-Income Households*, NY Furman Center for Real Estate & Urban Policy (February 2019) https://robcollinson.github.io/Robwebsite/jmp_rcollinson.pdf.

eligible for ERA funding and to delay lease terminations for any tenants whose application for ERA assistance is still pending after a 30-day period. Additionally, HUD notes that the Department of Justice issued guidance encouraging courts to consider postponing pending eviction cases to allow tenants to apply for emergency rental assistance.⁴⁸ For tenants who have already applied for such assistance, HUD would expect that courts may be even more inclined to postpone eviction proceedings. Further, a minimum 30-day time period may provide tenants with an opportunity to secure counsel to assist them in eviction proceedings. Given these factors, HUD believes that providing tenants with at least 30-days from the date of notification of lease termination and notification of the availability of emergency rental assistance will sufficiently help most tenants who are eligible for ERA to retain their housing, while ensuring PHAs and PBRA owners can operate effectively.

In determining that this interim final rule's requirement to provide the notice in the time period described above was the most appropriate means to achieve the goals discussed, the agency considered and rejected several other changes to its program requirements. For instance, HUD considered the imposition of an eviction moratorium in these programs, which would have allowed extensive time for tenants to seek ERA funding. HUD determined that its statutory authorities do not clearly provide the authority necessary to impose such a broad moratorium. By contrast, as noted above, HUD's authorities provide for the imposition of terms and conditions on public housing authorities and owners when those entities are exercising the discretion provided under the statute and their respective contracts to seek to collect rent and promptly take action for nonpayment of rent. HUD believes this more targeted action better accords with the statutory scheme, which gives landlords discretion to evict but provides HUD authority to regulate the prompt collection of rent and processing of evictions.

Additionally, HUD considered imposing a requirement on PHAs and owners to apply for emergency funding on behalf of tenants before proceeding with eviction. HUD also considered the use of required retroactive recertifications and required repayment plans for tenants who would qualify for

ERA assistance. HUD also considered tying the notification requirement on a more limited scale to a particular location, region or based on a specific finding that a jurisdiction had a high COVID rate. For all of these options, HUD has already worked with PHA and owners to encourage them to apply for ERA, allow recertifications, create repayment plans, and adjust to rents. However, HUD believed implementing these changes by regulation would be overly burdensome and create multiple challenges for implementation.

In deciding to act in the manner described in this interim final rule, HUD has based its actions on the enumerated authorities granted to it by statute. This interim final rule is consistent with HUD's statutory authority and is in keeping with the types of requirements imposed by HUD through its existing regulations.

IV. Findings and Certifications

Executive Orders 12866 and 13563, Regulatory Planning and Review

Pursuant to Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive order. This interim final rule has been determined to be a "significant regulatory action," as defined in section 3(f) of Executive Order 12866, but not economically significant. HUD has prepared a regulatory impact analysis that addresses the costs and benefits of the interim final rule. The analysis is available at www.regulations.gov and is part of the docket file for this rule.

Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. HUD believes that this interim final rule would provide added protections for tenants and is consistent with Executive Order 13563.

Executive Order 12612, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism

implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of Section 6 of the Executive order. This interim final rule would not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Environmental Impact

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

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities. Because HUD determined that good cause exists to issue this rule without prior public comment, this rule is not subject to the requirement to publish an initial or final regulatory flexibility analysis under the RFA as part of such action.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid Office of Management and Budget (OMB) control number. HUD requested emergency approval to OMB of the information collection changes described in this rule. HUD has published elsewhere in this issue of the **Federal Register** a separate notice for public comment informing the public of the additional burden associated with the existing collection for public housing OMB Control No: 2577–0006

⁴⁸ U.S. Dep't. of Justice, *Letter from Associate Attorney General Gupta*, June 24, 2021, <https://www.justice.gov/asg/page/file/1405886/download>.

and for multifamily housing OMB Control No: 2502-0178.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4; approved March 22, 1995) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This rule does not impose any Federal mandates on any state, local, or tribal government, or on the private sector, within the meaning of the UMRA.

List of Subjects

24 CFR Part 247

Grant programs—housing and community development, Loan programs—housing and community development, Low and moderate income housing, Rent subsidies.

24 CFR Part 880

Grant programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 882

Grant programs—housing and community development, Homeless, Lead poisoning, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 884

Grant programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements, Rural areas.

24 CFR Part 966

Grant programs—housing and community development, Public housing, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, HUD amends 24 CFR parts 247, 880, 882, 884, and 966 as follows:

PART 247—EVICTIONS FROM CERTAIN SUBSIDIZED AND HUD-OWNED PROJECTS

- 1. The authority citation for part 247 continues to read as follows:

Authority: 12 U.S.C. 1701q, 1701s, 1715b, 1715l, and 1715z-1; 42 U.S.C. 1437a, 1437c, 1437f, and 3535(d).

- 2. Amend § 247.4 by adding a sentence to the end of paragraph (c) and a sentence to the end of paragraph (e) to read as follows:

§ 247.4 Termination notice.

* * * * *

(c) * * * In cases of nonpayment of rent, if the Secretary determines that tenants must be provided with adequate notice to secure Federal funding that is available due to a Presidential declaration of a national emergency, the termination notice shall be effective no earlier than 30 days after receipt by the tenant of the termination notice.

* * * * *

(e) * * * Where the Secretary has made the determination in paragraph (c) of this section, the termination notice must provide such information as required by the Secretary.

* * * * *

PART 880—SECTION 8 HOUSING ASSISTANCE PAYMENT PROGRAM FOR NEW CONSTRUCTION

- 3. The authority citation for part 880 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), 12701, and 13611-13619.

- 4. Amend § 880.607 by adding paragraph (c)(6) to read as follows:

§ 880.607 Termination of tenancy and modification of lease.

* * * * *

(c) * * *

(6) In the case of failure to pay rent, if the Secretary determines that tenants must be provided with adequate notice to secure Federal funding that is available due to a Presidential declaration of a national emergency:

(i) The termination notice must provide such information as required by the Secretary; and

(ii) The notice must provide the tenant with at least 30 days before termination.

* * * * *

PART 882—SECTION 8 MODERATE REHABILITATION PROGRAMS

- 5. The authority citation for part 882 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

- 6. Amend § 882.511 by:

- a. Revising paragraph (d)(1)(i);
 ■ b. Adding paragraph (d)(2)(iv); and
 ■ c. In paragraph (d)(3), removing the reference to “paragraph (c)(2)” and adding the reference “paragraphs (d)(1) and (2) of this section” in its place.

The revision and addition read as follows:

§ 882.511 Lease and termination of tenancy.

* * * * *

(d) * * *

(1) * * *

(i) When termination is based on failure to pay rent, the date of termination must be not less than five working days after the Family’s receipt of the notice; or, if the Secretary determines that tenants must be provided with adequate notice to secure Federal funding that is available due to a Presidential declaration of a national emergency, the date of termination must be not less than 30 days after the Family’s receipt of the notice.

* * * * *

(2) * * *

(iv) Include such information to tenants during a national emergency, as required by the Secretary.

* * * * *

PART 884—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM, NEW CONSTRUCTION SET-ASIDE FOR SECTION 515 RURAL RENTAL HOUSING PROJECTS

- 7. The authority citation for part 884 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611-13619.

- 8. Amend § 884.216 by adding paragraph (d) to read as follows:

§ 884.216 Termination of tenancy.

* * * * *

(d) In the case of failure to pay rent, if the Secretary determines that tenants must be provided with adequate notice to secure Federal funding that is available due to a Presidential declaration of a national emergency:

(1) The owner must provide the tenant with written termination notification that includes such information as required by the Secretary; and

(2) The written termination notification described in paragraph (d)(1) of this section must be provided to the tenant at least 30 days before termination.

PART 966—PUBLIC HOUSING LEASE AND GRIEVANCE PROCEDURE

- 9. The authority citation for part 966 continues to read as follows:

Authority: 42 U.S.C. 1437d and 3535(d).

- 10. Add § 966.8 to read as follows:

§ 966.8 Providing opportunity to receive emergency rent relief.

(a) If the Secretary determines that tenants must be provided with adequate notice to secure Federal funding that is available due to a Presidential declaration of a national emergency:

(1) The notice of lease termination required in § 966.4(l)(3) for failure to

pay rent must provide such information as required by the Secretary; and

(2) Notwithstanding § 966.4(l)(3)(i)(A), the notice of lease termination for failure to pay rent must provide for at least 30 days from the date the tenant receives the notice.

(b) Upon the Secretary's determination in paragraph (a) of this section, the PHA must provide notice to all tenants of the requirements in paragraph (a) taking effect.

Dominique Blom,

General Deputy Assistant Secretary, Office of Public and Indian Housing.

Lopa P. Kolluri,

Principal Deputy Assistant Secretary, Office of Housing-Federal Housing Administration.

[FR Doc. 2021-21960 Filed 10-6-21; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2021-0748]

RIN 1625-AA08

Special Local Regulation; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for the San Diego Sharkfest Swim marine event that will be held on the navigable waters of San Diego Bay, San Diego, CA. This action is necessary to provide for the safety of life on these navigable waters of San Diego Bay during a swim event on October 10, 2021. This rule would prohibit spectators from anchoring, blocking, loitering or transiting through the event area unless authorized by the Captain of the Port San Diego or a designated representative.

DATES: This rule is effective from 8:30 a.m. to 10:30 a.m. on October 10, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0748 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management,

U.S. Coast Guard Sector San Diego, CA; telephone (619) 278-7656, email D11MarineEventsSD@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 we must establish this special local regulation by October 10, 2021. The Coast Guard was given short notice from the event sponsor that the date of the event would differ from the existing annual marine event as outlined in 33 CFR 100.1101, Table 1 to § 100.1101, Item 7. As such, it is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. This regulation is necessary to ensure the safety of life on the navigable waters of San Diego Bay during the marine event.

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 life on the navigable waters of San Diego Bay during the marine event on October 10, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041 (previously 33 U.S.C. 1236). The Captain of the Port Sector San Diego (COTP) has determined that a large amount of swimmers in San Diego Bay associated with the San Diego Sharkfest Swim marine event on October 10, 2021, poses a potential safety concern.

This rule is needed to protect persons, vessels, and the marine environment in the navigable waters within San Diego Bay while the event is occurring.

IV. Discussion of the Rule

This rule establishes a special local regulation from 8:30 a.m. to 10:30 a.m. on October 10, 2021. This special local regulation will cover the navigable waters of San Diego Bay encompassed by a line connecting the following coordinates beginning at 32°42'14" N, 117°09'55" W (Point A); thence running southerly to 32°41'49" N, 117°09'57" W (Point B); thence running south, along the shoreline to 32°41'19" N, 117°09'48" W (Point C); thence running north easterly to 32°41'23" N, 117°09'41" W (Point D); thence running northerly to 32°42'00" N, 117°09'38" (Point E); thence running northerly, along the shoreline to the beginning point. The duration of the zone is intended to ensure the safety of vessels, event participants, and these navigable waters during the scheduled marine event. No vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative. The regulatory text appears at the end of this document.

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 regulated area. The affected portion of the San Diego Bay will be of very limited duration, during morning hours when vessel traffic is historically low and is necessary for safety of life to participants in the event. Moreover, the Coast Guard would make a post in the Local Notice to Mariners with details on the regulated area, as well as, issue a

Safety Marine Information Broadcast over Channel 22A.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship

between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a regulated area that would limit access to certain areas of San Diego Bay from 8:30 a.m. to 10 a.m. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T11–0748 to read as follows:

§ 100.T11–0748 San Diego Sharkfest Swim, San Diego Bay, California.

(a) *Regulated area.* The regulations in this section apply to the following area: all navigable waters of San Diego Bay encompassed by a line connecting the following points beginning at 32°42′14″ N, 117°09′55″ W (Point A); thence running southerly to 32°41′49″ N, 117°09′57″ W (Point B); thence running south, along the shoreline to 32°41′19″ N, 117°09′48″ W (Point C); thence running north easterly to 32°41′23″ N, 117°09′41″ W (Point D); thence running northerly to 32°42′00″ N, 117°09′38″ (Point E); thence running northerly, along the shoreline to the beginning point. These coordinates are based on the 1984 World Geodetic System (WGS 84).

(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 San Diego (COTP) in the enforcement of the regulations in this section.

Participant means all persons and vessels registered with the event sponsor as a participants in the race.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port San Diego or their designated representative.

(2) Vessels requiring entry into this regulated area must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 21A or by telephone at 619–278–7033.

(3) The COTP will provide notice of the regulated area through advanced

notice via Local Notice to Mariners and Safety Marine Information Broadcasts on Channel 22A.

(d) *Enforcement period.* This section will be enforced from 8:30 a.m. to 10:30 a.m. on October 10, 2021.

Dated: September 29, 2021.

T.J. Barelli,

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

[FR Doc. 2021-21891 Filed 10-6-21; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2020-0581; FRL-8585-01-OCSPP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (21-2.B)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of premanufacture notices (PMNs). This action requires persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this rule. This action further requires that persons not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice (SNUN), EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any risk management actions as are required as a result of that determination.

DATES: This rule is effective on December 6, 2021. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on October 21, 2021.

FOR FURTHER INFORMATION CONTACT: For technical information contact: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: wysong.william@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422

South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. 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:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA, which would include the SNUR requirements. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. How can I access the docket?

The docket includes information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0581, is available at <https://www.regulations.gov> and at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. 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 OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

Due to the public health emergency, 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>.

II. Background

A. What action is the Agency taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for chemical substances which were the subject of PMNs P-19-82, P-20-76, and P-20-94. These SNURs require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

Previously, in the **Federal Register** of April 30, 2021 (86 FR 22924) (FRL-10017-51), EPA proposed SNURs for these chemical substances. More information on the specific chemical substances subject to this final rule can be found in the **Federal Register** document proposing the SNURs. The docket includes information considered by the Agency in developing the proposed and final rules, including public comments and EPA's responses to the public comments received on the proposed rules, as described in Unit IV.

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

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III.

C. Do the SNUR general provisions apply?

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by

TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit. During its review of these chemicals, EPA identified certain conditions of use that are not intended by the submitters, but reasonably foreseen to occur. EPA is designating those reasonably foreseen conditions of use as well as certain other circumstances of use as significant new uses.

IV. Public Comments

EPA received a public comment from one identifying entity on the proposed rule. The comment was broadly supportive and requested no changes to the final rule; therefore, no response is required. EPA made no changes to the final rule as a result of this comment.

V. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for chemical substances in 40 CFR part 721, subpart E. In Unit IV. of the proposed SNUR, EPA provided the following information for each chemical substance:

- PMN number.
 - Chemical name (generic name, if the specific name is claimed as CBI).
 - Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
 - Basis for the SNUR.
 - Potentially useful information.
 - CFR citation assigned in the regulatory text section of this final rule.
- The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the rules, may be claimed as CBI.

VI. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these SNURs and as further discussed in Unit IV. of the proposed rule, EPA identified certain other reasonably foreseen conditions of use in addition to those conditions of use intended by the submitter. EPA has determined that the chemical under the intended conditions of use is not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use. EPA is designating these conditions of use as well as certain other circumstances of use as significant new uses. As a result, those significant new uses cannot occur without going through a separate, subsequent EPA review and determination process associated with a SNUN.

B. Objectives

EPA is issuing these SNURs because the Agency wants:

- To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially

exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

- To be able to complete its review and determination on each of the PMN substances, while deferring analysis on the significant new uses proposed in these rules unless and until the Agency receives a SNUN.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at <https://www.epa.gov/tsca-inventory>.

VII. Applicability of the Rules to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule were undergoing premanufacture review at the time of signature of the proposed rule and were not on the TSCA inventory. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for the chemical substances subject to these SNURs, EPA concluded at the time of signature of the proposed rule that the designated significant new uses were not ongoing.

EPA designated December 4, 2020 (the date of web posting of the proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who began commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date will have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under TSCA section 5 allowing manufacture or processing to proceed.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.*, generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the proposed rule lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. of the proposed rule will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol election. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

The potentially useful information described in Unit IV. of the proposed rule may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However,

submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

IX. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket for this rulemaking.

XI. Statutory and Executive Order Reviews

Additional information about these statutes and executive orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

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

This action establishes SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to PRA, 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 that requires OMB approval under PRA,

unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

The listing of the OMB control numbers of the collection instruments and their subsequent codification in the table in 40 CFR 9.1 satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since this ICR was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table in 40 CFR part 9, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table in 40 CFR 9.1 without further notice and comment.

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b), 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of

SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018. Only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action will not have federalism implications because it is not expected to have a substantial direct effect on 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action will not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal

governments and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 30, 2021.

Tala Henry,
Deputy Director, Office of Pollution Prevention and Toxics.

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

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, amend the table by adding entries for §§ 721.11568 through 721.11570 in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

40 CFR citation	OMB control No.
*	*
Significant New Uses of Chemical Substances	
*	*
721.11568	2070-0012
721.11569	2070-0012
721.11570	2070-0012
*	*
*	*

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 4. Add §§ 721.11568 through 721.11570 to subpart E to read as follows:

Subpart E Significant New Uses for Specific Chemical Substances

* * * * *

Sec.

- 721.11568 Heptanal, 6-hydroxy-2,6-dimethyl-.
- 721.11569 Glycine, reaction products with sodium O-iso-Pr carbonodithioate, sodium salts.
- 721.11570 Aliphatic urethane methacrylate (generic).

* * * * *

§ 721.11568 Heptanal, 6-hydroxy-2,6-dimethyl-

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as heptanal, 6-hydroxy-2,6-dimethyl- (PMN P-19-82; CAS No. 62439-42-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to process the substance to a concentration of greater than or equal to 1.0% in the final end use formulation.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=14.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11569 Glycine, reaction products with sodium O-iso-Pr carbonodithioate, sodium salts.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as glycine, reaction products with sodium O-iso-Pr carbonodithioate, sodium salts (PMN P-20-76; CAS No. 2205080-23-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=21.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11570 Aliphatic urethane methacrylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified generically as aliphatic urethane methacrylate (PMN P-20-94) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63(a)(4), (5) and (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50 (or 1,000 for spray applications). For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate. The provisions of this paragraph (a)(2)(i) do not apply when both of the following conditions are met:

(A) The substance was manufactured with no greater than 3.5% acrylate feedstock by weight, and

(B) Any residual isocyanate in the substance is present at no greater than 0.1% by weight.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (d) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

* * * * *

[FR Doc. 2021-21858 Filed 10-6-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1502, 1512, 1513, 1516, 1532, 1539, and 1552

[EPA-HQ-OARM-2018-0714; FRL-9109-01-OMS]

Environmental Protection Agency Acquisition Regulation; Unenforceable Commercial Supplier Agreement Terms, Class Deviations, and Update for Fixed Rates for Services—Indefinite Delivery/Indefinite Quantity Contract

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to amend the Environmental Protection Agency Acquisition Regulation (EPAAR) to address common *Commercial Supplier Agreement* terms that are inconsistent with or create ambiguity with Federal Law, to create a new subpart for class deviations, and to update clause *Fixed Rates for Services—Indefinite Delivery/Indefinite Quantity Contract*.

DATES: This final rule is effective on October 7, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OARM-2018-0714. 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., 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 electronically through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Thomas Valentino, Policy, Training and Oversight Division, Acquisition Policy and Training Branch (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-4522; email address: valentino.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On September 17, 2019 (84 FR 48856) EPA sought public comments on the proposed rule and received no public comments.

(a) *Incompatibility of Commercial Supplier Agreements*

EPA defines *Commercial Supplier Agreements (CSAs)* as terms and

conditions that are customarily offered to the public by vendors of supplies or services that meet the Federal Acquisition Regulation (FAR) definition of *commercial item* and are intended to create a binding legal obligation on the end user. CSAs are common in information technology acquisitions, including acquisitions of commercial computer software and commercial technical data, and they may apply to any supply or service.

Commercial supplies and services are offered to the public under standard agreements that may take a variety of forms, including but not limited to license agreements, terms of service, and terms of sale or purchase. These standard CSAs contain terms and conditions that are appropriate when the purchaser is a private party, but not when the purchaser is the Federal Government.

The existence of federally-incompatible terms in standard CSAs is recognized in FAR 27.405–3(b), which is limited to the acquisition of commercial computer software. This subsection advises contracting officers to exercise caution when accepting a contractor's terms and conditions. The use of CSAs is not limited to information technology acquisitions, as they have become common in a broad variety of contexts, from travel to telecommunications, financial services, and building maintenance systems; including purchases below the simplified acquisition threshold.

Discrepancies between CSAs and Federal law, or the Government's needs, create recurrent points of inconsistency. Below are examples of incompatible clauses that are commonly found in CSAs:

- Jurisdiction or venue clauses may require that disputes be resolved in a particular state or a venue that otherwise conflicts with U.S. Federal law. Such clauses conflict with the sovereign immunity of the U.S. Government. Therefore, these clauses cannot apply to litigation where the U.S. Government is a defendant because those disputes must be heard either in the U.S. District Courts (28 U.S.C. 1346), the U.S. Court of Federal Claims (28 U.S.C. 1491), or a venue otherwise authorized by Federal law.
- Automatic renewal clauses may automatically renew or extend contracts unless affirmative action is taken by the Government. Such clauses that require the obligation of funds prior to appropriation violate the restrictions of the *Anti-Deficiency Act* (31 U.S.C. 1341(a)(1)(B)).
- Termination clauses may allow the contractor to unilaterally terminate a

contract if the Government is alleged to have breached the contract. Government contracts are subject to the *Contract Disputes Act* of 1978 (41 U.S.C. 601–613). The *Contract Disputes Act* requires a certain process for resolving disputes, including terminations, and that the “Contractor shall proceed diligently with performance of this contract, pending final resolution” under the terms of the FAR *Disputes* clause at 52.233–1.

Additionally, the current order of precedence contained in the *Commercial Items* clause at FAR 52.212–4 is not clear on prevailing terms, and potentially allows CSAs to supersede the terms of Federal contracts, especially in those areas where Federal law is implicated indirectly. As a result, industry and Government representatives must spend time and resources negotiating and tailoring CSAs to comply with Federal law and to ensure both parties reach an agreement on the contract terms.

(b) Value of Addressing Incompatible Commercial Supplier Agreements

EPA has identified common illegal, improper or inappropriate CSA terms that constitute the majority of the negotiated CSA terms. The outcome of the negotiations regarding these identified terms is generally predetermined by rule of law, but EPA and contractors must spend time and resources to negotiate these terms. By explicitly addressing common unenforceable terms within the *Commercial Items* clause at FAR 52.212–4 and clarifying prevailing terms in the order of precedence, it eliminates the need for negotiation of these common conflicting terms.

This approach will decrease the time needed for legal review prior to contract award and will reduce costs to both the Government and contractors. EPA believes that such an approach will benefit contractors, including small business concerns, by: (1) Decreasing proposal costs associated with negotiating the identified unenforceable CSA terms; (2) facilitating faster procurement and contract lead times, therefore decreasing the time it takes for contractors to make a return on their investment; (3) reducing administrative costs for companies that maintain alternate federally compliant CSAs; and (4) for small business concerns, it levels the playing field with larger competitors since negotiations will only be required if the CSA contains objectionable clauses outside of those already identified in proposed clause. Additionally, this approach ensures consistent application and

understanding of these unenforceable terms.

(c) EPA Class Deviation

EPA is issuing class deviations for two Federal Acquisition Regulation (FAR) clauses to address the order of precedence and CSA terms that are incompatible with Federal law. The class deviations not only protect EPA and contractors by uniformly addressing common unacceptable terms and reducing risk, but also by further streamlining the acquisition process and reducing administrative cost for commercial-item supplies and services. The class deviations also clarify the precedence of terms to ensure parties have a mutual understanding of the contract terms.

(d) Updates to § 1516.505(b) and § 1552.216–73

The EPA is updating clause 1552.216–73, *Fixed Rates for Services—Indefinite Delivery/Indefinite Quantity Contract*, to add Alternate I (which had previously been a deviation) to the Basic form. The deviation was issued in April 2018 and provides for contractors to be paid escalated rates for optional periods of performance. The deviation is amended into an alternate version because there is an ongoing need for the deviation. The corresponding prescription in § 1516.505(b) is being updated accordingly.

(e) New Subpart 1552.3

EPA is creating a new subpart 1552.3, *FAR and EPAAR Class Deviations*, that will contain FAR and EPAAR class deviations initiated by the EPA. As discussed in II(c) the EPA is creating two new FAR class deviations in this final rule that will be added to the new subpart: Class deviations for 52.212–4, *Contract Terms and Conditions—Commercial Items (FAR DEVIATION)*; and 52.232–39, *Unenforceability of Unauthorized Obligations (FAR DEVIATION)*.

II. Final Rule

The final rule amends the EPAAR to implement standard terms and conditions for the most common conflicting CSA terms and to minimize the need for the negotiation of these terms of CSAs on an individual basis. The final rule will add requirements to contracts making certain conflicting or inconsistent terms in a CSA unenforceable so long as an express exception is not authorized elsewhere by Federal statute. EPA is also amending the EPAAR to modify the order of precedence contained in the *Contract Terms and Conditions—*

Commercial Items clause (FAR 52.212–4) to make clear that the *Commercial Items—Unenforceable Clause* section of the EPAAR deviation clause controls in the event of a conflict with a CSA, unless both parties agree to specific terms during the course of negotiating the contract. The EPA is also amending the EPAAR to create new subpart 1552.3 for class deviations. The EPA is also changing the deviated version of clause 1552.216–73 into an alternate version because of its ongoing need.

These changes are accomplished by revising guidance and clauses contained throughout the EPAAR as follows:

- EPAAR § 1502.100 is amended to provide a definition for *Commercial Supplier Agreements*.
- EPAAR § 1512.101 is created and clarifies that paragraph (u) of the deviated *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) prevents violation of the *Anti-Deficiency Act*.
- EPAAR § 1512.1070 is created to prescribe the use of the deviated *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) in lieu of FAR 52.212–4.
- EPAAR § 1513.507(b) is amended and requires the inclusion of § 1552.332–39 and § 1552.232–75 in all acquisitions for supplies or services that are offered under a CSA.
- EPAAR Subpart 1513.6 is created and will add § 1552.332–39 to all purchases below the micro-purchase threshold.
- EPAAR § 1516.505(b) is amended to update the prescription for § 1552.216–73.
- EPAAR Subpart 1532.10 is created and clarifies the definition of *supplier license agreements* as used in FAR 32.705, *Unenforceability of Unauthorized Obligations*.
- EPAAR § 1532.1070 is created and directs contracting officers to utilize the clause at § 1552.332–39 in lieu of FAR 52.232–39; and prescribes the use of clause *Commercial Supplier Agreements—Unenforceable Clauses* at 1552.232–75.
- EPAAR Subpart 1539.1 is created and advises contracting officers and contract specialists to follow the relevant EPAAR rules relating to CSA procurement.
- EPAAR § 1552.216–73 is amended to add an alternate clause version.
- EPAAR § 1552.232–75 is created for non-commercial contracts and addresses the same common unenforceable CSA terms addressed in § 1552.312–4 (FAR DEVIATION) paragraph (w) described above.

- EPAAR Subpart 1552.3 is created and adds the class deviations for § 1552.312–4 and § 1552.332–39.

- The *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) in subpart 1552.3 is modified to include instructions to contracting officers on how to incorporate the change in language from FAR 52.212–4.

- The order of precedence contained in paragraph (s) of the *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) in subpart 1552.3 is amended to ensure that all of the terms of § 1552.312–4(w), *Commercial Supplier Agreements—unenforceable clauses*, shall control over the terms of a CSA by including “Commercial Supplier Agreements—Unenforceable Clauses” in § 1552.312–4(s)(2) and revising § 1552.212–4(s)(4) to say, “Addenda to this solicitation or contract, including any commercial supplier agreements as amended by the Commercial Supplier Agreements—Unenforceable Clauses provision.”

- Paragraph (u) of the *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) in subpart 1552.3 is amended to (1) reflect the new *Commercial Supplier Agreement* definition contained in EPAAR 1502.100; (2) expand coverage to “language or provision” in addition to “clause” in order to ensure that all CSA terms are covered regardless of terminology utilized; and (3) include future fees, penalties, interest and legal costs as unauthorized obligations in addition to indemnification.

- Paragraph (w) of the *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) in subpart 1552.3 is created to address the following commonplace unenforceable elements found in CSAs:

- *Definition of contracting parties:* Contract agreements are between the commercial supplier or licensor and the U.S. Government. Government employees or persons acting on behalf of the Government will not be bound in their personal capacity by the CSA.

- *Laws and disputes:* Clauses that conflict with the sovereign immunity of the U.S. Government cannot apply to litigation where the U.S. Government is a defendant because those disputes must be heard either in U.S. District Court or the U.S. Court of Federal Claims. CSA terms that require the resolution of a dispute in a forum or time period other than those expressly authorized by Federal law are deleted. Statutes of limitation on potential claims shall be governed by U.S. Federal law.

- *Continued Performance:* Commercial suppliers may not

unilaterally terminate or suspend a contract based upon a suspected breach of contract by the Government. These types of CSA terms violate 31 U.S.C. 3324, which provides that payment under a contract may not exceed the value of a service or product already delivered. A license that is prematurely terminated outside of the regular dispute resolution procedures results in the Government not receiving the value of that good or service ordered because it is no longer delivered. The removal of the contractor’s right to unilateral termination does not impair the contractor’s ability to pursue remedies. It preserves all the legal remedies the contractor otherwise has under Federal law, including *Contract Disputes Act* claims. Remedies through the *Contract Disputes Act* or other applicable Federal statutes align with the continuing performance requirement set forth in paragraph (d) *Disputes*.

- *Arbitration; equitable or injunctive relief:* A binding arbitration may not be enforced unless explicitly authorized by agency guidance or statute. Equitable remedies or injunctive relief such as attorney fees, cost or interest may only be awarded against the U.S. Government when expressly authorized by statute (e.g., *Prompt Payment Act*).

- *Additional Terms:* Incorporation of terms by reference is allowed provided the full text of terms is provided with the offer. Unilateral modifications to the CSA after the time of award may be allowed to the extent that the modified terms do not materially change the Government’s rights or obligations, increase the Government’s prices, decrease the level of service provided, or limit any Government right addressed elsewhere in the contract. A bilateral contract modification is required for any of the above described changes to be enforceable against the Government.

- *Automatic renewals:* Due to *Anti-Deficiency Act* restrictions, automatic contract renewal clauses are impermissible. Any such CSA clauses are unenforceable.

- *Indemnity (contractor assumes control of proceedings):* Any clause requiring that the commercial supplier or licensor control any litigation arising from the Government’s use of the contractor’s supplies or services is deleted. Such representation when the Government is a party is reserved by statute for the U.S. Department of Justice.

- *Audits (automatic liability for payment):* Discrepancies found during an audit must comply with the invoicing procedures from the underlying contract. Disputed charges must be resolved through the *Disputes*

clause. Any audits requested by the commercial supplier or licensor will be performed at supplier or licensor's expense.

○ *Taxes or surcharges*: Any taxes or surcharges that will be passed along to the Government will be governed by the terms of the underlying contract. The cognizant contracting officer must make a determination of applicability of taxes whenever such a request is made.

○ *Assignment of CSA or Government contract by supplier*: The contract, CSA, party rights and party obligations may not be assigned or delegated without express Government approval. Payment to a third party financial institution may still be reassigned.

○ *Confidentiality of CSA terms and conditions*: The content of the CSA may not be deemed confidential. The Government may retain other marked confidential information as required by law, regulation or agency guidance, but will appropriately guard such confidential information.

• § 1552.332–39 (FAR DEVIATION) in subpart 1552.3 is created to amend the language of FAR 52.232–39 to reflect the definition of CSAs contained at EPAAR 1502.100, to expand coverage to “language or provision” in addition to “clause” in order to ensure that all CSA terms are covered, regardless of terminology utilized; and to include future fees, penalties, interest and legal costs as unauthorized obligations in addition to indemnification.

This final rule will reduce risk by uniformly addressing common unacceptable CSA terms, facilitate efficiency and effectiveness in the contracting process by reducing the administrative burden for the Government and industry, and promote competition by reducing barriers to industry, including small businesses. It will also create a new EPAAR subpart for class deviations, and an alternate version for clause 1552.216–73.

III. Final Rule

The final rule amends Part 1502, *Definition of Words and Terms*, by adding a definition for *Commercial Supplier Agreements* to § 1502.100. It adds Part 1512, *Acquisition of Commercial Items*, Subpart 1512.1, *Special Requirements for the Acquisition of Commercial Items*, § 1512.101, *Unenforceability of Unauthorized Obligations*, and § 1512.1070, *Contract Clause*. It amends Part 1513, *Simplified Acquisition Procedures*, by adding Subpart 1513.6, *Action At or Below the Micropurchase Threshold*, and amending § 1513.507(b). It amends § 1516.505(b) by adding an alternate clause version to the clause

prescription. It amends Part 1532, *Contract Financing*, by adding Subpart 1532.10, *Unenforceability of Unauthorized Obligations*; and § 1532.1070, *Contract Clauses*. It amends Part 1539, *Acquisition of Information Technology*, and adds Subpart 1539.1, *Commercial Supplier Agreements*. It amends Subpart 1552.2, *Texts of Provisions and Clauses*, by adding an alternate clause version to § 1552.216–73, *Fixed Rates for Services—Indefinite Delivery/Indefinite Quantity Contract*; and adding § 1552.232–75, *Commercial Supplier Agreements—Unenforceable Clauses*. Finally, it amends Part 1552, *Solicitation Provisions and Contract Clauses*, by adding Subpart 1552.3, *FAR and EPAAR Class Deviations*, and class deviations for clauses 52.212–4 and 52.232–39. This final rule:

1. Amends part 1502, *Definition of Words and Terms*, by adding a definition for *Commercial Supplier Agreements* to § 1502.100, *Definitions*.

2. Adds part 1512, *Acquisition of Commercial Items*, and subpart 1512.1, *Special Requirements for the Acquisition of Commercial Items*, which clarify that paragraph (u) of the *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) prevents violation of the *Anti-Deficiency Act*.

3. Adds § 1512.101, *Unenforceability of Unauthorized Obligations*, and § 1512.1070, *Contract Clause*, to prescribe the use of the deviated *Commercial Items* clause at § 1552.312–4 (FAR DEVIATION) in lieu of FAR 52.212–4.

4. Amends part 1513, *Simplified Acquisition Procedures*, by adding Subpart 1513.6, *Action At or Below the Micropurchase Threshold*, and amending § 1513.507(b), which will automatically apply the clauses at § 1552.232–75 and § 1552.332–39 to all purchases below the micro-purchase threshold.

5. Amends the currently designated § 1513.507(a) to become § 1513.507(a)(i), and the currently designated § 1513.507(b) to become § 1513.507(a)(ii), due to the addition above.

6. Amends § 1516.505(b) by adding an alternate clause version to the prescription.

7. Adds EPAAR Subpart 1532.10, *Unenforceability of Unauthorized Obligation*, that clarifies the definition of supplier license agreements.

8. Adds EPAAR § 1532.1070 and establishes the prescription for use of EPAAR clause 1552.232–75 in all procurements where supplies or services are offered under a CSA.

9. Amends part 1539, *Acquisition of Information Technology*, and adds

subpart 1539.1, *Commercial Supplier Agreements*.

10. Amends subpart 1552.2, *Texts of Provisions and Clauses*, to add an alternate clause version to § 1552.216–73, *Fixed Rates for Services—Indefinite Delivery/Indefinite Quantity Contract*, that pays the contractor escalated rates for optional periods of performance.

11. Adds EPAAR § 1552.232–75, *Commercial Supplier Agreements—Unenforceable Clauses*, that provides the terms and conditions for supplies or services offered under a CSA.

12. Adds EPAAR subpart 1552.3, *FAR and EPAAR Class Deviations*, to contain § 1552.312–4, *Contract Terms and Conditions—Commercial Items (FAR DEVIATION)*; and § 1552.332–39/*Unenforceability of Unauthorized Obligations (FAR DEVIATION)*.

§ 1552.312–4 updates paragraphs (s) and (u), and adds paragraph (w). § 1552.332–39 updates terms from *Terms of Sale* and *End User Licensing Agreement* to *Commercial Supplier Agreement*.

IV. Statutory and Executive Orders Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a “significant regulatory action” under the terms of Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the E.O.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute; unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impact of this proposed rule on small entities, “small entity” is defined as: (1) A small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a

government of a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives “which minimize any significant economic impact of the proposed rule on small entities” 5 U.S.C. 503 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This action creates a new EPAAR clause, clause alternate and class deviations that will not have a significant economic impact on a substantial number of small entities, as discussed in Section (II)(B). We continue to be interested in the potential impacts of the rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4), establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and Local officials in the development of regulatory policies that have federalism implications. “Policies that have federalism implications” is defined in the Executive Order to

include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132.

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

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This rule does not have tribal implications as specified in Executive Order 13175.

G. Executive Order 13045: Protecting Children From Environmental Health and Safety Risks

Executive Order 13045, entitled “Protection of Children from Environmental Health and Safety Risks” (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be economically significant as defined under E.O. 12886, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions on environment health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use” (66 FR 28335 (May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) (15 U.S.C. 272 note) of the National Technology Transfer and Advancement Act of 1995, Public Law 104–113, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be

inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment in the general public.

List of Subjects in 48 CFR Parts 1502, 1512, 1513, 1516, 1532, 1539, and 1552

Environmental protection, Accounting, Government procurement, Reporting and recordkeeping requirements.

Kimberly Patrick,

Director, Office of Acquisition Solutions.

Therefore, 48 CFR chapter 15 is amended as follows:

PART 1502—DEFINITION OF WORDS AND TERMS

■ 1. The authority citation for part 1502 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

■ 2. Amend § 1502.100 by adding in alphabetical order a definition for “Commercial supplier agreements (CSA)” to read as follows:

1502.100 Definitions.

* * * * *

Commercial supplier agreements (CSAs) mean terms and conditions customarily offered to the public by vendors of supplies or services that meet the definition of “commercial item” set forth in FAR 2.101 and intended to create a binding legal obligation on the end user. CSAs are common in information technology acquisitions, including acquisitions of commercial computer software and commercial technical data, and they may apply to any supply or service. CSAs may apply regardless of the format or style of the document (for example, a CSA may be styled as *standard terms of sale or lease*, *Terms of Service (TOS)*, *End User License Agreement (EULA)*, or another similar legal instrument or agreement, and may be presented as part of a proposal or quotation responding to a solicitation for a contract or order). CSAs may also apply regardless of the media or delivery mechanism used (for example, a CSA may be presented as one or more paper documents, or may appear on a computer or other electronic device screen during a purchase, software installation, product delivery, registration for a service, or other transaction).

* * * * *

- 3. Add part 1512 to subchapter B read as follows:

PART 1512—ACQUISITION OF COMMERCIAL ITEMS**Subpart 1512.1—Special Requirements for the Acquisition of Commercial Items**

Sec.

1512.101 Unenforceability of unauthorized obligations.

1512.1070 Contract clause.

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

Subpart 1512.1—Special Requirements for the Acquisition of Commercial Items**1512.101 Unenforceability of unauthorized obligations.**

EPA deviates from FAR 52.212–4 by using the term *Commercial Supplier Agreements* (defined in 1502.100) for commercial contracts instead of *supplier license agreements*. Paragraph (u) of clause 1552.332–39 (FAR DEVIATION) prevents violations of the *Anti-Deficiency Act* (31 U.S.C. 1341) for the acquisition of supplies or services subject to a Commercial Supplier Agreement.

1512.1070 Contract clause.

EPA deviates from FAR 52.212–4 by revising paragraphs (s) and (u) and

adding paragraph (w). Contracting officers shall use clause 1552.332–39, *Contract Terms and Conditions-Commercial Items* (FAR DEVIATION), for acquisitions of commercial items in lieu of 52.212–4 or 52.212–4 Alternate I. The contracting officer may tailor this clause in accordance with FAR 12.302.

PART 1513—SIMPLIFIED ACQUISITION PROCEDURES

- 4. The authority citation for part 1513 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

- 5. Add subpart 1513.6 to read as follows:

Subpart 1513.6—Actions at or Below the Micro-Purchase Threshold

Unenforceability of unauthorized obligations in micro-purchases. Clause 1552.332–39, *Unenforceability of Unauthorized Obligations* (FAR DEVIATION), will automatically apply to any micro-purchase in lieu of nondeviated FAR 52.232–39 for supplies and services acquired subject to a commercial supplier agreement (as defined in 1502.100).

- 6. Revise 1513.507 to read as follows:

1513.507 Contract clauses.

(a)(i) It is the general policy of the Environmental Protection Agency that contractor or vendor prescribed leases or maintenance agreements for equipment shall not be executed.

(ii) The contracting officer shall, where appropriate, insert the clause at 1552.213–70, *Notice to Suppliers of Equipment*, in orders for purchases or leases of automatic data processing equipment, word processing, and similar types of commercially available equipment for which vendors, as a matter of routine commercial practice, have developed their own leases and/or customer service maintenance agreements.

(b) Where the supplies or services are offered under a Commercial Supplier Agreement (as defined in 1502.100), the purchase order or modification shall incorporate clause 1552.332–39, *Unenforceability of Unauthorized Obligations* (FAR DEVIATION), in lieu of nondeviated clause 52.232–39, and clause 1552.232–75, *Commercial Supplier Agreements-Unenforceable Clauses*.

PART 1516—TYPES OF CONTRACTS

- 7. The authority citation for part 1516 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

- 8. Amend 1516.505 by revising paragraph (b) to read as follows:

1516.505 Contract clauses.

* * * * *

(b) The contracting officer shall insert clause substantially the same as 1552.216–73, *Fixed Rates for Services—Indefinite Delivery/Indefinite Quantity Contract*, in solicitations and contracts to specify fixed rates for services. Contracting officers may use Alternate I for procurements that will have order performance periods longer than one year. Alternate I has a different paragraph (c) from the Basic form. Contracting officers must use the Basic form as prescribed for procurements that will have orders with performance periods of one year or less. Contracting officers may use both the Basic form and Alternate I for procurements that will have mixed-length orders, where some are for one year or less, and others are for longer than one year. In such cases contracting officers must include procurement language that the Basic form applies to orders less than one year, and Alternate I applies to orders longer than one year.

PART 1532—CONTRACT FINANCING

- 9. The authority citation for part 1532 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

- 10. Add subpart 1532.10 to read as follows:

Subpart 1532.10—Unenforceability of Unauthorized Obligations

Supplier license agreements defined in FAR 32.705 are equivalent to *Commercial Supplier Agreements* defined in 1502.100.

1532.1070 Contract Clauses.

(a) The contracting officer shall utilize the clause at 1552.332–39, *Unenforceability of Unauthorized Obligations* (FAR DEVIATION) in all solicitations and contracts in lieu of nondeviated FAR 52.232–39.

(b) The contracting officer shall utilize the clause at 1552.232–75, *Commercial Supplier Agreements-Unenforceable Clauses*, in all procurements where supplies or services are offered under a commercial supplier agreement (CSA).

PART 1539—ACQUISITION OF INFORMATION TECHNOLOGY

- 11. The authority citation for part 1539 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

■ 12. Add subpart 1539.1 to read as follows:

Subpart 1539.1—Commercial Supplier Agreements

(a) *Background*—(i) *Commercial Supplier Agreements (CSAs)* are defined at 1502.100, in part, as terms and conditions that are customarily offered to the public by vendors of supplies or services that meet the definition of *commercial item* and are intended to create a binding legal obligation on the end user. CSAs are common in information technology acquisitions, including acquisitions of commercial computer software and commercial technical data, and they may apply to any supply or service.

(ii) Commercial supplies and services are offered to the public under standard agreements that may take a variety of forms, including, but not limited to, *license agreements, terms of service, and terms of sale or purchase*. These standard CSAs contain terms and conditions that are appropriate when

the purchaser is a private party, but not when the purchaser is the Federal Government. The existence of federally-incompatible terms in standard CSAs is recognized in FAR 27.405–3(b), which states contracting officers should exercise caution in accepting a vendor’s terms and conditions, since they may be written for commercial sales and not appropriate for Government contracts. *(Note that the use of CSAs is not limited to information technology acquisitions, as they have become common in a broad variety of contexts, from travel to telecommunications to financial services to building maintenance systems; including purchases below the simplified acquisition threshold.)*

(b) *Policy*. The EPAAR includes standard terms and conditions for the most common conflicting CSA terms, and contracting officers and contract specialists must follow the relevant rules in parts 1512, 1513, and 1532 when purchasing information technology that includes a CSA. Contracting Officers must review CSAs submitted by offerors/contractors. FAR deviations 1552.312–4 and 1552.332–39

apply to many common conflicting CSA terms, but not all conflicting terms. Therefore, all submitted CSAs must be reviewed by the contracting officer and the Office of General Counsel (OGC).

PART 1552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 13. The authority citation for part 1552 continues to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

■ 14. Revise 1552.216–73 to read as follows:

1552.216–73 Fixed rates for services— indefinite delivery/indefinite quantity contract.

As prescribed in 1516.505(b), insert the following clause:

FIXED RATES FOR SERVICES— INDEFINITE DELIVERY/INDEFINITE QUANTITY CONTRACT (OCT. 2021)

(a) The following fixed rates shall apply for payment purposes for the duration of the contact.

Personnel classification	Skill level	Fixed hourly rate

(b) The rate, or rates, set forth in paragraph (a) of this section cover all expenses, including report preparation, salaries, overhead, general and administrative expenses, and profit.

(c) The Contractor shall voucher for only the time of the personnel whose services are applied directly to the work called for in individual Orders and accepted by the EPA Contracting Officer’s Representative (COR). The Government shall pay the Contractor for the life of the Order at rates in effect when the Order was issued, even if performance under the Order crosses into another period. The Contractor shall maintain time and labor distribution records for all employees who work under the contract. These records must

document time worked and work performed by each individual on all Orders.

(End of Clause)

Alternate I (date). As prescribed in 1515.505(b), modify the Basic form of the clause by changing paragraph (c) to the following:

(c) The Contractor shall voucher for only the time of the personnel whose services are applied directly to the work called for in individual Orders and accepted by the EPA Contracting Officer’s Representative (COR). The Government shall pay the Contractor at rates in effect when the work is

performed by the Contractor. The Contractor shall maintain time and labor distribution records for all employees who work under the contract. These records must document time worked and work performed by each individual on all Orders.

■ 15. Add 1552.232–75 to subpart 1552.2 to read as follows:

1552.232–75 Commercial supplier agreements—unenforceable clauses.

As prescribed in 1513.507(b) and 1532.1070 insert the following clause:

COMMERCIAL SUPPLIER AGREEMENTS—UNENFORCEABLE CLAUSES (OCT. 2021)

When any supply or service acquired under this contract is subject to a Commercial Supplier Agreement (CSA, as defined in 48 CFR 1502.100), the following language shall be deemed incorporated into the CSA. As used herein, “this agreement” means the CSA:

(a) Notwithstanding any other provision of this agreement, when the end user is an agency or instrumentality of the U.S. Government, the following shall apply:

(1) *Applicability.* This agreement is part of a contract between the commercial supplier and the U.S. Government for the acquisition of the supply or service that necessitates a license or other similar legal instrument (including all contracts, task orders, and delivery orders under FAR Parts 13, 14 or 15).

(2) *End user.* This agreement shall bind the ordering activity as end user but shall not operate to bind a Government employee or person acting on behalf of the Government in his or her personal capacity.

(3) *Law and disputes.* This agreement is governed by Federal law.

(i) Any language purporting to subject the U.S. Government to the laws of a U.S. state, U.S. territory, district, or municipality, or foreign nation, except where Federal law expressly provides for the application of such laws, is hereby deleted.

(ii) Any language requiring dispute resolution in a specific forum or venue that is different from that prescribed by applicable Federal law is hereby deleted.

(iii) Any language prescribing a different time period for bringing an action than that prescribed by applicable Federal law in relation to a dispute is hereby deleted.

(4) *Continued performance.* The supplier or licensor shall not unilaterally revoke, terminate or suspend any rights granted to the Government except as allowed by this contract. If the supplier or licensor believes the ordering activity to be in breach of the agreement, it shall pursue its rights under the *Contract Disputes Act* or other applicable Federal statute while continuing performance as set forth in FAR 52.233-1, *Disputes*.

(5) *Arbitration; equitable or injunctive relief.* In the event of a claim or dispute arising under or relating to this agreement, a binding arbitration shall not be used unless specifically authorized by agency guidance, and equitable or injunctive relief, including the award of attorney fees, costs or interest, may be awarded against the U.S. Government only when explicitly provided by statute (e.g., *Prompt Payment Act* or *Equal Access to Justice Act*).

(6) *Updating terms.* (i) After award, the contractor may unilaterally revise terms if they are not material. A material change is defined as:

- (A) Terms that significantly change Government rights or obligations; and
- (B) Terms that increase Government prices;
- (C) Terms that decrease overall level of service; or
- (D) Terms that limit any other Government right addressed elsewhere in this contract.

(ii) For revisions that will materially change the terms of the contract, the revised commercial supplier agreement must be incorporated into the contract using a bilateral modification.

(iii) Any agreement terms or conditions unilaterally revised subsequent to award that are inconsistent with any material term or provision of this contract shall not be enforceable against the Government, and the Government shall not be deemed to have consented to them.

(7) *No automatic renewals.* If any license or service tied to periodic payment is provided under this agreement (e.g., annual software maintenance or annual lease term), such license or service shall not renew automatically upon expiration of its current term without prior express consent by an authorized Government representative.

(8) *Indemnification.* Any clause of this agreement requiring the commercial supplier or licensor to defend or indemnify the end user is hereby amended to provide that the U.S. Department of Justice has the sole right to represent the United States in any such action, in accordance with 28 U.S.C. 516.

(9) *Audits.* Any clause of this agreement permitting the commercial supplier or licensor to audit the end user's compliance with this agreement is hereby amended as follows:

(i) Discrepancies found in an audit may result in a charge by the commercial supplier or licensor to the ordering activity. Any resulting invoice must comply with the proper invoicing requirements specified in the underlying Government contract or order.

(ii) This charge, if disputed by the ordering activity, will be resolved through the *Disputes* clause at FAR 52.233-1; no payment obligation shall arise on the part of the ordering activity until the conclusion of the dispute process.

(iii) Any audit requested by the contractor will be performed at the contractor's expense, without reimbursement by the Government.

(10) *Taxes or surcharges.* Any taxes or surcharges which the commercial supplier or licensor seeks to pass along to the Government as end user will be governed by the terms of the underlying Government contract or order and, in any event, must be submitted to the Contracting Officer for a determination of applicability prior to invoicing unless specifically agreed to otherwise in the Government contract.

(11) *Non-assignment.* This agreement may not be assigned, nor may any rights or obligations thereunder be delegated, without the Government's prior approval, except as expressly permitted under the clause at FAR 52.232-23, *Assignment of Claims*.

(12) *Confidential information.* If this agreement includes a confidentiality clause, such clause is hereby amended to state that neither the agreement nor the contract price list, as applicable, shall be deemed “confidential information.” Issues regarding release of “unit pricing” will be resolved consistent with the *Freedom of Information Act*. Notwithstanding anything in this agreement to the contrary, the Government may retain any confidential information as required by law, regulation or its internal document retention procedures for legal,

regulatory or compliance purposes; provided, however, that all such retained confidential information will continue to be subject to the confidentiality obligations of this agreement.

(b) If any language, provision or clause of this agreement conflicts or is inconsistent with the preceding paragraph (a) of this clause, the language, provisions, or clause of paragraph (a) shall prevail to the extent of such inconsistency.

(End of Clause)

■ 16. Add subpart 1552.3, consisting of 1552.312-4 and 1552.332-39, to read as follows:

Subpart 1552.3—FAR and EPAAR Class Deviations

1552.312-4 Contract terms and conditions—commercial items (far deviation).

As prescribed in 1512.1070, the contracting officer shall insert clause 1552.332-39, *Contract Terms and Conditions-Commercial Items* (FAR DEVIATION), for acquisitions of commercial items in lieu of 52.212-4 or 52.212-4 Alternate I. The contracting officer may tailor this clause in accordance with FAR 12.302.

CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS (FAR DEVIATION) (OCT. 2021)

(a) *Inspection/acceptance.* The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights—

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(b) *Assignment.* The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the *Assignment of Claims Act* (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) *Changes.* Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) *Disputes.* This contract is subject to 41 U.S.C. chapter 71, *Contract Disputes*. Failure

of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, *Disputes*, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) *Definitions*. The clause at FAR 52.202-1, *Definitions*, is incorporated herein by reference.

(f) *Excusable delays*. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) *Invoice*. (1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include—

- (i) Name and address of the Contractor;
- (ii) Invoice date and number;
- (iii) Contract number, line item number and, if applicable, the order number;
- (iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
- (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
- (vi) Terms of any discount for prompt payment offered;
- (vii) Name and address of official to whom payment is to be sent;
- (viii) Name, title, and phone number of person to notify in event of defective invoice; and
- (ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, *Payment by Electronic Funds Transfer—System for Award Management*, or 52.232-34, *Payment by Electronic Funds Transfer—Other Than System for Award Management*), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the *Prompt Payment Act* (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.

(h) *Patent indemnity*. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) *Payment*—(1) *Items accepted*. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) *Prompt payment*. The Government will make payment in accordance with the *Prompt Payment Act* (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(3) *Electronic Funds Transfer (EFT)*. If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) *Discount*. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) *Overpayments*. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

- (A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);
- (B) Affected contract number and delivery order number, if applicable;
- (C) Affected line item or subtitle item, if applicable; and
- (D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) *Interest*. (i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) *Final decisions*: The Contracting Officer will issue a final decision as required by 33.211 if—

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

- (A) The date fixed under this contract.
- (B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—

- (A) The date on which the designated office receives payment from the Contractor;
- (B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or
- (C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) *Risk of loss*. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

- (1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or
- (2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) *Taxes*. The contract price includes all applicable Federal, State, and local taxes and duties.

(l) *Termination for the Government's convenience*. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the

satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) *Termination for cause.* The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) *Title.* Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) *Warranty.* The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) *Limitation of liability.* Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) *Other compliances.* The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) *Compliance with laws unique to Government contracts.* The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, *Contract Work Hours and Safety Standards*; 41 U.S.C. chapter 87, *Kickbacks*; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, *Fly American*; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) *Order of precedence.* Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services.

(2) The *Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, Unauthorized Obligations, and Commercial Supplier Agreements-Unenforceable Clauses* paragraphs of this clause.

(3) The clause at 52.212-5.

(4) Addenda to this solicitation or contract, including any commercial supplier agreements as amended by the *Commercial*

Supplier Agreements—Unenforceable Clauses provision.

(5) Solicitation provisions if this is a solicitation.

(6) Other paragraphs of this clause.

(7) The Standard Form 1449.

(8) Other documents, exhibits, and attachments.

(9) The specification.

(t) [Reserved]

(u) *Unauthorized Obligations.* (1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any commercial supplier agreement (as defined in 1502.100) that includes any language, provision, or clause requiring the Government to pay any future fees, penalties, interest, legal costs or to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an *Anti-Deficiency Act* violation (31 U.S.C. 1341), the following shall govern:

(i) Any such language, provision, or clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the commercial supplier agreement. If the commercial supplier agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such language, provision, or clause is deemed to be stricken from the commercial supplier agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification or any other payment by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) *Incorporation by reference.* The Contractor's representations and certifications, including those completed electronically via the *System for Award Management* (SAM), are incorporated by reference into the contract.

(w) *Commercial Supplier Agreements—unenforceable clauses.* When any supply or service acquired under this contract is subject to a *Commercial Supplier Agreement* (as defined in 48 CFR 1502.100), the following language shall be deemed incorporated into the commercial supplier agreement. As used herein, "this agreement" means the Commercial Supplier Agreement:

(1) Notwithstanding any other provision of this agreement, when the end user is an agency or instrumentality of the U.S. Government, the following shall apply:

(i) *Applicability.* This agreement is a part of a contract between the commercial supplier and the U.S. Government for the acquisition of the supply or service that necessitates a license or other similar legal instrument (including all contracts, task orders, and delivery orders under FAR Part 12).

(ii) *End user.* This agreement shall bind the ordering activity as end user but shall not operate to bind a Government employee or person acting on behalf of the Government in his or her personal capacity.

(iii) *Law and disputes.* This agreement is governed by Federal law.

(A) Any language purporting to subject the U.S. Government to the laws of a U.S. state, U.S. territory, district, or municipality, or a foreign nation, except where Federal law expressly provides for the application of such laws, is hereby deleted.

(B) Any language requiring dispute resolution in a specific forum or venue that is different from that prescribed by applicable Federal law is hereby deleted.

(C) Any language prescribing a different time period for bringing an action than that prescribed by applicable Federal law in relation to a dispute is hereby deleted.

(iv) *Continued performance.* The supplier or licensor shall not unilaterally revoke, terminate or suspend any rights granted to the Government except as allowed by this contract. If the supplier or licensor believes the ordering activity to be in breach of the agreement, it shall pursue its rights under the Contract Disputes Act or other applicable Federal statute while continuing performance as set forth in paragraph (d) of this clause.

(v) *Arbitration; equitable or injunctive relief.* In the event of a claim or dispute arising under or relating to this agreement, a binding arbitration shall not be used unless specifically authorized by agency guidance, and equitable or injunctive relief, including the award of attorney fees, costs or interest, may be awarded against the U.S. Government only when explicitly provided by statute (e.g., *Prompt Payment Act* or *Equal Access to Justice Act*).

(vi) *Updating terms.* (A) After award, the contractor may unilaterally revise terms if they are not material. A material change is defined as:

(1) Terms that change Government rights or obligations;

(2) Terms that increase Government prices;

(3) Terms that decrease overall level of service; or

(4) Terms that limit any other Government right addressed elsewhere in this contract.

(B) For revisions that will materially change the terms of the contract, the revised commercial supplier agreement must be incorporated into the contract using a bilateral modification.

(C) Any agreement terms or conditions unilaterally revised subsequent to award that are inconsistent with any material term or provision of this contract shall not be enforceable against the Government, and the Government shall not be deemed to have consented to them.

(vii) *No automatic renewals.* If any license or service tied to periodic payment is provided under this agreement (e.g., annual software maintenance or annual lease term), such license or service shall not renew automatically upon expiration of its current term without prior express consent by an authorized Government representative.

(viii) *Indemnification.* Any clause of this agreement requiring the commercial supplier or licensor to defend or indemnify the end user is hereby amended to provide that the U.S. Department of Justice has the sole right to represent the United States in any such action, in accordance with 28 U.S.C. 516.

(ix) *Audits.* Any clause of this agreement permitting the commercial supplier or

licensor to audit the end user's compliance with this agreement is hereby amended as follows:

(A) Discrepancies found in an audit may result in a charge by the commercial supplier or licensor to the ordering activity. Any resulting invoice must comply with the proper invoicing requirements specified in the underlying Government contract or order.

(B) This charge, if disputed by the ordering activity, will be resolved in accordance with paragraph (d) of this clause; no payment obligation shall arise on the part of the ordering activity until the conclusion of the dispute process.

(C) Any audit requested by the contractor will be performed at the contractor's expense, without reimbursement by the Government.

(x) *Taxes or surcharges.* Any taxes or surcharges which the commercial supplier or licensor seeks to pass along to the Government as end user will be governed by the terms of the underlying Government contract or order and, in any event, must be submitted to the Contracting Officer for a determination of applicability prior to invoicing unless specifically agreed to otherwise in the Government contract.

(xi) *Non-assignment.* This agreement may not be assigned, nor may any rights or obligations thereunder be delegated, without the Government's prior approval, except as expressly permitted under paragraph (b) of this clause.

(xii) *Confidential information.* If this agreement includes a confidentiality clause, such clause is hereby amended to state that neither the agreement nor the contract price list, as applicable, shall be deemed "confidential information." Issues regarding release of "unit pricing" will be resolved consistent with the Freedom of Information Act. Notwithstanding anything in this agreement to the contrary, the Government may retain any confidential information as required by law, regulation or its internal document retention procedures for legal, regulatory or compliance purposes; provided, however, that all such retained confidential information will continue to be subject to the confidentiality obligations of this agreement.

(2) If any language, provision, or clause of this agreement conflicts or is inconsistent with paragraph (w)(1) of this clause, the language, provisions, or clause of paragraph (w)(1) shall prevail to the extent of such inconsistency.

(End of clause)

1552.332–39 Unenforceability of unauthorized obligations (far deviation).

As prescribed in 1513.507(b) and 1532.1070, use clause 1552.332–39 (FAR DEVIATION) instead of the nondeviated version for purchase orders, modifications and contracts that include commercial supplier agreements.

UNENFORCEABILITY OF UNAUTHORIZED OBLIGATIONS (FAR DEVIATION) (OCT. 2021)

(a) Except as stated in paragraph (b) of this clause, when any supply or service acquired

under this contract is subject to any commercial supplier agreement (as defined in 1502.100) that includes any language, provision, or clause requiring the Government to pay any future fees, penalties, interest, legal costs or to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an *Anti-Deficiency Act* violation (31 U.S.C. 1341), the following shall govern:

(1) Any such language, provision, or clause is unenforceable against the Government.

(2) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such language, provision, or clause by virtue of it appearing in the commercial supplier agreement. If the commercial supplier agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(3) Any such language, provision, or clause is deemed to be stricken from the commercial supplier agreement.

(b) Paragraph (a) of this clause does not apply to indemnification or any other payment by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(End of clause)

[FR Doc. 2021–21629 Filed 10–6–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 382, 383, 384, 390, and 392

[Docket No. FMCSA–2017–0330]

RIN 2126–AC11

Controlled Substances and Alcohol Testing: State Driver's Licensing Agency Non-Issuance/Downgrade of Commercial Driver's License

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA is amending its regulations to establish requirements for State Driver's Licensing Agencies (SDLAs) to access and use information obtained through the Drug and Alcohol Clearinghouse (DACH or Clearinghouse), an FMCSA-administered database containing driver-specific controlled substance (drug) and alcohol records. SDLAs must not issue, renew, upgrade, or transfer a commercial driver's license (CDL), or

commercial learner's permit (CLP), as applicable, for any individual prohibited under FMCSA's regulations from performing safety-sensitive functions, including driving a commercial motor vehicle (CMV), due to one or more drug and alcohol program violations. Further, SDLAs must remove the CLP or CDL privilege from the driver's license of an individual subject to the CMV driving prohibition, which would result in a downgrade of the license until the driver complies with return-to-duty (RTD) requirements. This rule also requires States receiving Motor Carrier Safety Assistance Program (MCSAP) grant funds to adopt a compatible CMV driving prohibition applicable to CLP and CDL holders who violate FMCSA's drug and alcohol program requirements and makes clarifying and conforming changes to current regulations. The final rule will help keep unsafe drivers off the road by increasing compliance with the CMV driving prohibition.

DATES:

Effective date: November 8, 2021.

Compliance date: Compliance with the final rule is required November 18, 2024.

Petitions for Reconsideration of this final rule must be submitted to the FMCSA Administrator no later than November 8, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Gian Marshall, Drug and Alcohol Programs Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, clearinghouse@dot.gov, (202) 366–0928. If you have questions on viewing material in the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

- I. Rulemaking Documents
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 - G. E.O. 13132 (Federalism)
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 - J. National Environmental Policy Act of 1969

I. Rulemaking Documents

Availability of Rulemaking Documents

To view any documents mentioned as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2017-0330/document> and choose the document to review. To view comments, click this final rule, then click "Browse Comments." If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

II. Executive Summary

A. Purpose and Summary of the Regulatory Action

The purpose of this final rule is to improve highway safety by ensuring that CLP or CDL holders with drug and alcohol program violations do not operate a CMV until they complete the return to duty (RTD) process and can lawfully resume driving. Currently, most SDLAs do not receive drug and alcohol program violation information about CDL or CLP holders licensed in their State. Therefore, these SDLAs are unaware when a CMV operator is subject to the driving prohibition set forth in 49 CFR 382.501(a), and the CMV operator continues to hold a valid CDL or CLP despite the driving prohibition.¹ The rule closes that knowledge gap by ensuring that all SDLAs are able to determine whether CMV drivers licensed in their State are subject to FMCSA's CMV driving

¹ As discussed further below in section V.C., several States currently require motor carrier employers or their service agents to report positive test results and/or test refusals to the SDLA.

prohibition. The rule facilitates enforcement of the driving prohibition by requiring that SDLAs deny certain commercial licensing transactions and remove the commercial driving privileges of individuals who are prohibited from operating a CMV and performing other safety-sensitive functions, due to drug and alcohol program violations. By requiring SDLAs to downgrade the driver's licensing status by removing the commercial driving privilege, the final rule will also permit all traffic safety enforcement officers to readily identify prohibited drivers by conducting a license check during a traffic stop or other roadside intervention.

In the final rule titled "Commercial Driver's License Drug and Alcohol Clearinghouse" (81 FR 87686 (Dec. 5, 2016)), FMCSA implemented the statutory requirement of the Moving Ahead for Progress in the 21st Century Act (MAP-21), codified at 49 U.S.C. 31306a, to establish the Clearinghouse as a repository for driver-specific drug and alcohol program violation records, as well as RTD information. The 2016 final rule incorporated the statutory requirement, imposed by MAP-21, codified at 49 U.S.C. 31311(a)(24), that States check the Clearinghouse prior to renewing or issuing a CDL to avoid having Federal highway funds withheld under 49 U.S.C. 31314. The 2016 final rule did not otherwise address the SDLAs' use of Clearinghouse information for CMV drivers licensed, or seeking to become licensed, in their State. This final rule establishes requirements for SDLAs to access and use information from the Clearinghouse indicating that CLP or CDL holders or applicants may not lawfully operate a CMV because they violated the drug and alcohol use and testing prohibitions in 49 CFR part 382, subpart B. The rule also makes certain clarifying and conforming changes to existing regulations, as described below.

B. Summary of Major Provisions

Non-Issuance

As noted above, the Clearinghouse regulations require that SDLAs check the driver's status by querying the Clearinghouse prior to issuing, renewing, transferring, or upgrading a CDL.² The final rule provides that, if the reply to the query indicates the driver is prohibited from operating a CMV, the SDLA must deny the requested commercial licensing transaction, resulting in non-issuance. Drivers may

² See 49 CFR 383.73(b)(10); (c)(10); (d)(9); (e)(8); and (f)(4).

re-apply to complete the transaction after complying with the RTD requirements set forth in 49 CFR part 40, subpart O, and a negative RTD test result has been reported to the Clearinghouse. As discussed further below, the rule extends the SDLAs' query requirement to applicants seeking to obtain, renew, or upgrade a CLP.

Mandatory CDL Downgrade

In addition to the non-issuance requirement, the rule requires that SDLAs initiate the process to remove the CLP or CDL privilege from the driver's license after receiving notification from FMCSA that, in accordance with 49 CFR 382.501(a), an individual is prohibited from operating a CMV. Pursuant to 49 CFR 383.5, "CDL downgrade" is defined to include removal of the commercial privilege;³ the final rule requires the State to complete and record the CDL downgrade on the CDLIS driver record within 60 days of notification. The CDL downgrade requirement rests on the simple, but safety-critical, premise that drivers who cannot lawfully operate a CMV because they engaged in prohibited use of drugs or alcohol or refused a test should not hold a valid CDL or CLP.

There are two ways the SDLA will receive notification of the driver's prohibited status: (1) The SDLA "pulls" the information from the Clearinghouse by conducting a required query prior to a specified commercial licensing transaction; and (2) FMCSA "pushes" the information to the SDLA whenever a drug or alcohol program violation is reported to the Clearinghouse for a CLP or CDL holder licensed in that State. FMCSA will also "push" a notification to the SDLA when the driver complies with RTD requirements and is no longer prohibited by FMCSA's regulations⁴ from operating a CMV. In addition, if FMCSA determines that a driver was erroneously identified as prohibited, the Agency will notify the SDLA that the individual is not prohibited from operating a CMV; the SDLA must promptly reinstate the commercial driving privilege to the driver's license, and expunge the driving record accordingly.

The final rule does not establish specific downgrade or reinstatement procedures. All States currently have established procedures to downgrade

³ In 49 CFR 383.5, "CDL downgrade" is defined, in part, as: "(4) A State removes the CDL privilege from the driver license." The final rule amends this definition to include removal of the CLP privilege.

⁴ The impact of MAP-21 and this rule on existing State requirements is discussed below in Section V.C.

the CDL or CLP of a driver whose medical certification has expired or otherwise been invalidated, as required by 49 CFR 383.73(o)(4). The Agency anticipates that States will adapt their existing processes to remove the CLP or CDL credential from the license of any driver subject to the CMV driving prohibition set forth in 49 CFR 382.501(a), and to reinstate the commercial privilege following receipt of notification from FMCSA that the individual is no longer prohibited from driving a CMV (or was incorrectly identified as prohibited).

Application of the State Query Requirement to CLP Holders

Pursuant to 49 CFR 383.25, CLPs are deemed a valid CDL for purposes of behind-the-wheel training on public roads and highways. Because CLP holders are authorized to operate a CMV on a public road if accompanied by a CDL holder, they are subject to drug and alcohol testing under 49 CFR part 382, and thus subject to the CMV driving prohibition in 49 CFR 382.501(a). Accordingly, the final rule adds CLP holders to the scope of the States' query requirements set forth in 49 CFR 383.73, requiring SDLAs to conduct a check of the Clearinghouse prior to issuing, renewing, or upgrading a CLP.

Addition of the CMV Driving Prohibition to Part 392

The final rule amends 49 CFR part 392, subpart B, "Driving of Commercial Motor Vehicles," to add the CMV driving prohibition currently set forth in 49 CFR 382.501(a), thereby requiring States receiving MCSAP funding to adopt and enforce a comparable prohibition.⁵ State-based MCSAP personnel authorized to enforce highway safety laws can electronically access the operating status of a CLP or CDL holder through *cdlis.dot.gov* or Query Central. If, during a roadside intervention, the MCSAP officer determines the driver is prohibited from operating a CMV due to a drug and alcohol program violation, the driver will be placed out-of-service and subject to citation. The final rule will further facilitate enforcement of the driving prohibition for CMV operators who still hold a valid CLP or CDL—*i.e.*, during the period in which the State is notified of the driver's prohibited status, but before the downgrade has been recorded

⁵ In order to qualify for MCSAP Funds, 49 CFR 350.207(a)(2) requires, in part, that States adopt and enforce State laws compatible with the Federal Motor Carrier Safety Regulations (49 CFR parts 390–397). Amending part 392 in the final rule will provide State-based enforcement personnel specific authority to enforce the prohibition in 382.501(a).

on the CDLIS driver record—by clarifying the basis for citing the CMV operator during this period.

As explained in the notice of proposed rulemaking (NPRM), some non-MCSAP traffic safety enforcement personnel cannot electronically access the driver's prohibited status at roadside during this period.⁶ The Agency notes, however, that after the SDLA completes the downgrade, thereby changing the driver's license status, non-MCSAP officers will be aware the driver is not lawfully operating a CMV, simply by conducting a routine license check. Operating a CMV without a valid CDL is currently prohibited under 49 CFR 383.23(a)(2) and 49 CFR 391.11(b)(5). The downgrade requirement ensures the CMV driver's license status is available to all traffic safety enforcement personnel, thus closing the loophole that currently permits these drivers to evade detection.

Actual Knowledge Violations Based on Issuance of a Citation for DUI in a CMV

The final rule revises how employers' reports of *actual knowledge*, as currently defined in 49 CFR 382.107, of a driver's prohibited use of drugs or alcohol, based on a citation for Driving Under the Influence (DUI) in a CMV, would be maintained in the Clearinghouse. Currently, employers who have actual knowledge of a driver's prohibited use of drugs or alcohol, based on the issuance of a citation or other document charging DUI in a CMV, must report the "actual knowledge" violation to the Clearinghouse in accordance with 49 CFR 382.705(b)(4). The final rule clarifies that a CLP or CDL holder who is charged with DUI in a CMV has violated part 382, subpart B, regardless of whether the driver is ultimately convicted of the offense. Therefore, the driver is prohibited from operating a CMV until completing RTD. The rule amends the Clearinghouse regulations by requiring that this type of actual knowledge violation remain in the Clearinghouse for 5 years, or until the driver has completed RTD, whichever is later, regardless of whether the driver is convicted of the DUI charge.⁷ The rule also permits drivers to add documentary evidence of non-

⁶ See 85 FR 23670, 23682 (Apr. 28, 2020). Nationwide, there are approximately 12,000 State-based MCSAP traffic safety officers, who have specialized knowledge and training related to CMV safety. There are also more than 500,000 State and local safety personnel throughout the United States authorized to enforce traffic safety laws.

⁷ 49 CFR 382.717(a)(2)(i) currently permits drivers to request that an actual knowledge violation, based on the issuance of a citation for DUI in a CMV, be removed from the Clearinghouse, when the citation did not result in a conviction.

conviction to their Clearinghouse record so that future employers will be aware of that outcome. FMCSA makes this change to fully comply with the MAP-21 requirements that all violations of part 382, subpart B, be reported to the Clearinghouse and retained for 5 years (49 U.S.C. 31306a(a)(3), (g)(1)(C), and (g)(6)(A), (B)), and to provide full disclosure to employers, while maintaining fairness to drivers.

Compliance Date

States must achieve substantial compliance with the applicable requirements of the final rule as soon as practicable, but not later than November 18, 2024. The requirements set forth in 49 CFR 390.3, 390.3T, and 392.15 amend the Federal Motor Carrier Safety Regulations (FMCSRs). In accordance with the MCSAP eligibility requirements in 49 CFR 350.303(b), the State must amend its laws or regulations to ensure compatibility with any new addition or amendment to the FMCSRs as soon as practicable, but not later than 3 years after the effective date of such changes. The Agency believes a 3-year period also allows States sufficient time to adopt necessary changes in State law and regulation, conduct training for SDLA personnel, and complete information technology (IT) changes that will allow SDLAs to request and receive Clearinghouse information electronically. This time frame also accounts for FMCSA's development of technical specifications that will allow the information to be efficiently and securely transmitted to the SDLAs, via CDLIS or a direct web-based interface with the Clearinghouse. In the meantime, SDLAs may determine whether a CLP or CDL applicant is qualified to operate a CMV by accessing the Clearinghouse as an authorized user, as currently permitted by 49 CFR 382.725(a)(1).

C. Costs and Benefits

This rule will result in IT costs for SDLAs, the American Association of Motor Vehicle Administrators (AAMVA), and the Federal government, customer service costs for SDLAs, and opportunity costs for drivers and motor carriers. This rule finalizes the Agency's preferred alternative by requiring a mandatory downgrade, while allowing the SDLAs to choose the most cost beneficial method of information transmission.

In the NPRM, FMCSA proposed two alternative methods for information transmission; CDLIS and a web-based services option, which relies on cloud technology. The Agency estimated that the CDLIS option would be more costly

to implement. Under the final rule, SDLAs may choose between transmitting information via CDLIS or a web-based services platform. FMCSA anticipates that SDLA costs for IT system development will depend on many variables and could range from \$60,000 to \$300,000. For analysis purposes, the Agency estimates that each SDLA will incur IT development costs of approximately \$200,000 in the first year of the analysis, and operation and maintenance costs equal to 20 percent of development cost in each of years 2 through 10. Two States also indicated they will incur costs to manage additional customer service inquiries related to the mandatory downgrade. FMCSA estimates that the annual cost for all SDLAs to manage additional customer service inquiries will total approximately \$159,000. In addition to SDLA costs, AAMVA indicated it may incur costs for aligning the Clearinghouse information with disqualification data that already exists

in CDLIS. FMCSA will work with AAMVA to determine the necessity and extent of these costs, but for analysis purposes estimates that they would not be greater than \$200,000 for development, with an annual operations and maintenance cost of \$40,000. FMCSA will incur costs of approximately \$1 million for development of a web-based services application and approximately \$200,000 for annual operations and maintenance costs in years 2 through 10 of the analysis. Under the final rule, a driver may incur an opportunity cost equal to the income forgone between the time he or she is eligible to resume operating a CMV (*i.e.*, when an employer reports a negative RTD test result to the Clearinghouse) and when the SDLA reinstates the driver's privilege to operate a CMV. The estimate of opportunity costs drivers may incur is a function of the number of drivers that may be subject to a downgrade, the time spent at the SDLA to reinstate their

CLP/CDL privileges, the forgone wages, and the travel costs to drive to and from the SDLA. As discussed in Section XI. below, FMCSA estimates that, annually, approximately 5,000 drivers will spend one 10-hour day at the SDLA, resulting in annual costs for all drivers of approximately \$1.6 million. Motor carrier opportunity costs are estimated because drivers subject to reinstatement would not be eligible to resume safety-sensitive functions, such as driving a CMV, until the SDLA restores the CLP or CDL privilege to the driver's license. FMCSA estimates that motor carrier opportunity cost resulting from this rule will total just below \$200,000 per year.

The table below shows the 10-year and annualized total cost estimates for the final rule. The Agency estimates the 10-year total cost of the rule at \$51.7 million; the estimated annualized cost is \$5.2 million. At a 7 percent discount rate, the 10-year total estimated cost is \$38.5 million, and the estimated annualized cost is \$5.5 million.

TABLE 1—TOTAL 10-YEAR AND ANNUALIZED COSTS OF THE FINAL RULE

Cost category	Undiscounted (2019 \$ million)		Discounted at 7% (\$ million)	
	10-year total cost	Annualized	10-year total cost	Annualized
SDLA Cost	\$30.1	\$3.0	\$23.1	\$3.3
AAMVA IT Cost	0.6	0.1	0.4	0.1
Federal Government IT Cost	2.8	0.3	2.2	0.3
Driver Opportunity Cost	16.4	1.6	11.5	1.6
Motor Carrier Opportunity Cost	1.8	0.2	1.3	0.2
Total	51.7	5.2	38.5	5.5

This rule will improve the enforcement of the current driving prohibition by requiring that States refrain from issuing, renewing, transferring, or upgrading the CLP or CDL of affected drivers. Removal of the commercial privilege from the driver's license (mandatory CLP or CDL downgrade) will ensure more consistent roadside enforcement against drivers who continue to operate a CMV in violation of the prohibition. The mandatory downgrade may also reduce drug and alcohol program violations, since a driver's loss of the commercial privilege directly impacts his or her ability to obtain employment that involves operating a CMV. This rule will also permit the Agency to use its enforcement resources more effectively. The final rule's costs and benefits are addressed further below in Section XI.

III. Abbreviations and Acronyms

AAMVA American Association of Motor Vehicle Administrators

ATA American Trucking Associations
 CA DMV California (CA) Department of Motor Vehicles
 CFR Code of Federal Regulations
 CDL Commercial Driver's License
 CDLIS Commercial Driver's License Information System
 CLP Commercial Learner's Permit
 CMV Commercial Motor Vehicle
 DACH or Clearinghouse Drug and Alcohol Clearinghouse
 DOT Department of Transportation
 DUI Driving Under the Influence
 FMCSA Federal Motor Carrier Safety Administration
 FR Federal Register
 Greyhound Greyhound Lines Inc.
 Illinois Office of the Illinois Secretary of State
 IOT Intensive Outpatient Treatment
 Iowa DOT Iowa Department of Transportation
 IT Information Technology
 MCSAP Motor Carrier Safety Assistance Program
 MDOJ—MVD Montana Department of Justice—Motor Vehicle Division
 Nebraska State of Nebraska Department of Motor Vehicles

NMFTA National Motor Freight Traffic Association
 Nlets The International Justice and Public Safety Network
 NRCME National Registry of Certified Medical Examiners
 NSTA The National School Transportation Association
 NYS DMV New York State Department of Motor Vehicles
 OOIDA Owner-Operator Independent Drivers Association
 Oregon Oregon Department of Transportation, Driver and Motor Vehicle Services
 RTD Return to Duty
 SDLA State Driver's Licensing Agency
 Secretary U.S. Secretary of Transportation
 Texas DPS State of Texas, Department of Public Safety
 TCA Truckload Carriers Association
 Trucking Alliance The Alliance for Driver Safety & Security
 U.S.C. United States Code
 Virginia DMV Commonwealth of Virginia, Department of Motor Vehicles

IV. Legal Basis for the Rulemaking

Title 49 of the Code of Federal Regulations (CFR), sections 1.87(e) and (f), delegates authority to the FMCSA Administrator to carry out the functions vested in the Secretary of Transportation (the Secretary) by 49 U.S.C. chapter 313 and 49 U.S.C. chapter 311, subchapters I and III, relating to CMV programs and safety regulations.

MAP-21 identified the remedial purposes of the Clearinghouse as twofold: To improve compliance with the drug and alcohol program applicable to CMV operators and to improve roadway safety by “reducing accident and injuries involving the misuse of alcohol or use of controlled substances” by CMV operators (49 U.S.C. 31306(a)(2)). As noted above, MAP-21 requires that the Secretary establish a national clearinghouse for records relating to alcohol and controlled substances testing by CMV operators who hold CDLs. The Agency implemented that requirement in the “Commercial Driver’s License Drug and Alcohol Clearinghouse” final rule (81 FR 87686 (Dec. 5, 2016)). MAP-21 also requires that the Secretary establish a process by which the States can request and receive an individual’s Clearinghouse record, for the purpose of “assessing and evaluating the qualifications of the individual to operate a commercial motor vehicle” (49 U.S.C. 31306(h)(2)). MAP-21 (49 U.S.C. 31311(a)(24)) requires that States request information from the Clearinghouse before renewing or issuing a CDL to an individual to avoid having Federal highway funds withheld under 49 U.S.C. 31314. This final rule establishes the processes by which SDLAs will access DACH information to determine whether the driver has the qualifications to operate a CMV. (Drivers prohibited from operating a CMV under 49 CFR 382.501(a) are not so qualified.)

The rule is also based on FMCSA’s broad authority in 49 U.S.C. chapter 313, (provisions originally enacted as part of the Commercial Motor Vehicle Safety Act of 1986 (1986 Act)). Section 31308 requires the Secretary, through regulation, to establish minimum standards for the issuance of CLPs and CDLs by the States. The final rule requires that States must not issue a CLP or CDL to an individual prohibited, under 49 CFR 382.501(a), from operating a CMV due to a drug and alcohol program violation. Pursuant to this same authority, the rule also establishes standards for the States’ removal of the CLP or CDL privilege

from the driver’s license of such individuals, as well as subsequent reinstatement of the commercial privilege.

Section 31305(a) requires the Secretary to establish minimum standards for, among other things, “ensuring the fitness of an individual operating a commercial motor vehicle.” In order to avoid having Federal highway funds withheld under 49 U.S.C. 31314, section 31311(a)(1) requires States to adopt and carry out a program for testing and ensuring the fitness of individuals to operate CMVs consistent with the minimum standards imposed by the Secretary under 49 U.S.C. 31305(a).

The final rule will help ensure the fitness of CMV operators by requiring that States must not issue, renew, transfer, or upgrade a CDL, or issue, renew, or upgrade a CLP, for any driver prohibited from operating a CMV due to a drug and alcohol program violation. Driver fitness is further ensured by the final rule’s requirement that States remove the CLP or CDL privilege from the driver’s licenses of individuals who violate the Agency’s drug and alcohol program requirements, until those drivers complete the RTD requirements established by 49 CFR part 40, subpart O.

The Department’s drug and alcohol use and testing regulations are authorized by 49 U.S.C. 31306 (originally enacted as part of the Omnibus Transportation Employee Testing Act of 1991). Among other things, 49 U.S.C. 31306(f) authorizes the Secretary to determine “appropriate sanctions for a commercial motor vehicle operator who is found, based on tests conducted and confirmed under this section, to have used alcohol or a controlled substance” in violation of applicable use testing requirements (*i.e.*, 49 CFR parts 40 and 382). As explained elsewhere in this preamble, FMCSA believes that non-issuance, as well as the mandatory downgrade, are appropriate sanctions that will improve compliance with existing drug and alcohol program requirements.

This final rule also relies on the authority of 49 U.S.C. chapter 311, subchapter III (provisions originally enacted as part of the Motor Carrier Safety Act of 1984), which provides concurrent authority to regulate drivers, motor carriers, and vehicle equipment. Section 31136(a) requires the Secretary to prescribe safety standards for CMVs which, at a minimum, shall ensure that: (1) CMVs are maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on CMV operators do not impair their ability to

operate the vehicles safely; (3) the physical condition of the CMV operators is adequate to enable them to operate vehicles safely; (4) CMV operation does not have a deleterious effect on the physical condition of the operators; and (5) CMV drivers are not coerced by a motor carrier, shipper, receiver, or transportation intermediary to operate a CMV in violation of the regulations promulgated under 49 U.S.C. 31136 or 49 U.S.C. chapters 51 or 313 (49 U.S.C. 31136(a)).

The final rule will help ensure that CMVs are “operated safely,” as mandated by section 31136(a)(1), and that the physical condition of CMV operators is adequate to enable their safe operation, as required by section 31136(a)(3). The requirement that States enforce the CMV driving prohibition on individuals who engage in prohibited use of drugs or alcohol will promote the safe operation of CMVs. Specifically, it will improve compliance with current regulatory requirements set forth in 49 CFR 382.501(a) and 382.503, which prohibit a CLP or CDL holder from operating a CMV, or performing other safety-sensitive functions, after engaging in prohibited use of drugs or alcohol, until the driver has completed the RTD requirements established by 49 CFR part 40, subpart O. The final rule does not directly address the operational responsibilities imposed on CMV drivers (section 31136(a)(2)) or possible physical effects caused by driving (section 31136(a)(4)). FMCSA has no reason to believe that the final rule will result in the coercion of CMV drivers by motor carriers, shippers, receivers, or transportation intermediaries (section 31136(a)(5)), as the rule primarily concerns the transmission of Clearinghouse information between FMCSA and the States, and the use of that information by the SDLAs and State-based traffic safety enforcement personnel. The Agency notes, however, that the 2016 Clearinghouse final rule prohibits employers from submitting false violation reports to the Clearinghouse, or from using Clearinghouse information for any purpose other than determining whether a driver is prohibited from operating a CMV, which could have coercive effects on drivers.⁸

Before prescribing regulations, FMCSA must consider their “costs and benefits” and “State laws and regulations on commercial motor vehicle safety, to minimize their unnecessary preemption” (section 31136(c)(2)). Those factors are addressed elsewhere in this preamble.

⁸ See 49 CFR 382.705(e), 382.723.

V. Background

The NPRM addressed the MAP–21 mandates underlying the 2016 Clearinghouse final rule (identified above), the MAP–21 provisions addressing the preemption of State laws, the Agency’s interpretation of those provisions, and the AAMVA petition for reconsideration of the 2016 final rule (see 85 FR 23670, 23675–23677, 23679 (Apr. 28, 2020)). The elements of that discussion most relevant to this final rule are summarized below.

A. Purpose and Intent of State-Related Clearinghouse Requirements

Though the CDL program was established by Federal statute (the 1986 Act) and is governed in part by Federal regulations (49 CFR parts 383 and 384), the authority to issue and remove CDLs and CLPs resides solely in the States. As explained in the NPRM, FMCSA considers the separate MAP–21 provisions requiring that (1) States request information from the Clearinghouse before renewing or issuing a CDL to an individual (49 U.S.C. 31311(a)(24)); and (2) the Secretary establish a process enabling State licensing authorities to access the Clearinghouse to determine whether an individual applying for a CDL is qualified to operate a CMV (49 U.S.C. 31306a(h)(2)(B)(ii)), as two parts of an integrated whole.⁹ Both provisions implicitly recognize that only SDLAs may act on commercial licenses.¹⁰

FMCSA acknowledges that neither of these State-specific statutory provisions requires that States restrict the issuance of commercial licenses or endorsements of CMV operators subject to the driving prohibition in 49 CFR 382.501(a), or that States downgrade the CDLs of drivers subject to the prohibition. However, in promulgating this final rule, FMCSA does not view the two State-related MAP–21 provisions in a vacuum. The stated goals of the Clearinghouse are to

⁹ This interpretation clarifies the Agency’s views expressed in the 2016 Clearinghouse final rule. See 81 FR 87686, 87708 (Dec. 5, 2016). In discussing the two statutory provisions, both of which contemplate that SDLAs would have access to Clearinghouse information, FMCSA characterized section 31311(a)(24) as requiring access and 31306a(h)(2) as permitting such access, viewing the separate requirements as inconsistent. In the Clearinghouse final rule, FMCSA ultimately required States to access the Clearinghouse prior to issuing CDLs. As noted above, in this final rule, FMCSA views the two provisions as part of a unified statutory scheme.

¹⁰ The term *Chief Commercial Driver’s Licensing Official* is defined as “the official in a State who is authorized to (A) maintain a record about commercial driver’s licenses issued by the State; and (B) take action on commercial driver’s licenses issued by the State” (49 U.S.C. 31306a(m)(2)) (emphasis supplied).

increase compliance with existing DOT-regulated drug and alcohol program requirements and to improve highway safety by reducing crashes and injuries caused by the misuse of drugs or alcohol by CMV drivers (49 U.S.C. 31306a(a)(2)). And MAP–21 authorizes SDLAs to access Clearinghouse information and requires SDLAs to request information from the Clearinghouse before renewing or issuing a CDL to an individual. With this framework in mind, and given the fact that commercial licensing authority is vested exclusively in the States, FMCSA relies on 49 U.S.C. 31306a and 31311(a)(24), as well as FMCSA’s authority under 49 U.S.C. 31305(a) and 31308, to require that States use their licensing authority to help ensure compliance with the CMV driving prohibition. This final rule thus achieves the broad remedial purpose of MAP–21, *i.e.*, the reduction of risk to public safety caused by CMV operators who are prohibited from driving due to drug and alcohol program violations but continue to be commercially licensed.

B. AAMVA’s Petition for Reconsideration

Following FMCSA’s publication of the 2016 Clearinghouse final rule, AAMVA, asserting that “[t]he authority for taking action based on federal clearinghouse records should remain solely with the employer and FMCSA,”¹¹ requested that FMCSA remove SDLAs from the scope of the rule. In response, the Agency explained that, because MAP–21 requires the States to access Clearinghouse information in order to avoid a loss of funds apportioned from the Highway Trust Fund (49 U.S.C. 31311(a)(24)), MAP–21 did not vest in FMCSA the discretion to “remove” the States from the Clearinghouse process.¹² Further, the Agency does not have authority to issue or remove CDLs, which is exclusively a State function.

In its petition, AAMVA also identified questions and concerns related to the States’ role in the Clearinghouse, which were not addressed in the 2016 final rule. These included: What specific information would States receive about

¹¹ See AAMVA Petition for Reconsideration of the Commercial Driver’s License Drug and Alcohol Clearinghouse Final Rule (June 29, 2017), Docket No. FMCSA–2011–0031. AAMVA petitioned for reconsideration of the Clearinghouse final rule but did not submit the petition within 30 days after publication of the rule in the *Federal Register*, as required by 49 CFR 389.35(a). Therefore, in accordance with 49 CFR 389.35(a), the Agency considers AAMVA’s submission to be a petition for rulemaking submitted under 49 CFR 389.31.

¹² See Letter from Raymond Martinez (FMCSA) to Anne Ferro (AAMVA) (Apr. 12, 2018), p. 2, Docket No. FMCSA–2011–0031.

an individual CDL holder or applicant; how would States be expected to use information they receive from the Clearinghouse; how would the privacy of driver-specific Clearinghouse information transmitted to the States be protected; how would erroneous Clearinghouse information be corrected; to what extent would foreign-licensed drivers be included in the query and reporting process; and what would be the cost implications for the SDLAs. FMCSA agreed that AAMVA raised legitimate issues regarding the States’ use of driver-specific Clearinghouse information and granted AAMVA’s request for regulatory clarification. This final rule addresses the issues identified by AAMVA.

C. Impact of MAP–21 on State Laws

MAP–21 expressly preempts State laws and regulations that are inconsistent with the Clearinghouse regulations, including State-based requirements for “the reporting of violations of valid positive results from alcohol screening tests and drug tests,” as well as alcohol and drug test refusals and other violations of part 382, subpart B (49 U.S.C. 31306a(l)(1) and (2)). The Agency interprets 49 U.S.C. 31306a(l)(1) and (2) to mean that State-based reporting requirements inconsistent with the reporting requirements in 49 CFR 382.705 are preempted. As noted in the NPRM, as of 2018, at least eight States required that, for testing conducted in accordance with 49 CFR part 382 or part 40, CDL holders’ positive test results and/or test refusals be reported to the SDLA. States uncertain about whether their reporting requirements are inconsistent with preemption provisions set forth in 49 U.S.C. 31306a(l)(1) and (2) may request an advisory opinion from the Agency.

MAP–21 specifically excepts from preemption State requirements relating to “an action taken with respect to a commercial motor vehicle operator’s commercial driver’s license or driving record” due to violations of FMCSA’s drug and alcohol program requirements (49 U.S.C. 31306a(l)(3)). FMCSA is aware, for example, that at least three States currently disqualify CDL holders who test positive or refuse a drug or alcohol test regulated under 49 CFR part 382 or part 40, from operating a CMV until completing RTD requirements. Based on its interpretation of 49 U.S.C. 31306a(l)(3), the Agency believes that State-based requirements such as these likely fall within the scope of the statutory exception because they relate to an action taken on a CDL.

As discussed further below, in Section VI. B., *Meaning of the Term CDL*

Downgrade, the downgrade requirement, based on the authority of 49 U.S.C. 31305(a) and 31308, is the minimum action States must take, to avoid having Federal highway funds withheld under 49 U.S.C. 31314, to remove the CLP or CDL privilege from the license of drivers prohibited from operating a CMV due to a drug and alcohol program violation. Consistent with the MAP-21 preemption exception in 49 U.S.C. 31306a(l)(3), the final rule does not prohibit States from taking an alternative licensing action (e.g., suspension, revocation, disqualification) to accomplish the removal of the commercial privilege.

The final rule also affords States maximum flexibility to maintain the driving records of individuals who are prohibited from operating a CMV due to a drug and alcohol program violation. The final rule does not require any State action related to the driving record, other than the requirement that States record the downgrade on the CDLIS driver record within 60 days of receiving notification of a CLP or CDL holder's prohibited status. States will determine whether the reason for the downgrade (or other discretionary licensing action), or the individual's prohibited CMV driving status, is posted on a CMV operator's driving record, and for how long the information would remain.

VI. Discussion of Proposed Rulemaking and Comments

A. Proposed Rulemaking

On April 28, 2020, FMCSA published in the **Federal Register** (Docket No. FMCSA-2017-0330, (85 FR 23670)) an NPRM titled "Controlled Substances and Alcohol Testing: State Driver's Licensing Agency Non-Issuance/Downgrade of Commercial Driver's License." The NPRM proposed to prohibit SDLAs from issuing, renewing, transferring, or upgrading a CDL or CLP for any driver banned from operating a CMV under 49 CFR 382.501(a) ("non-issuance"). Further, the Agency proposed two alternatives addressing how SDLAs would receive and use Clearinghouse information pertaining to CDL or CLP holders licensed in their State who are prohibited from operating a CMV: (1) FMCSA's preferred alternative, a "push" notification of the driver's prohibited status and the SDLA's mandatory downgrade of the driver's license; or (2) permitting SDLAs the option to receive notification of a driver's prohibited status, with the State determining whether, and how, the information would be used to enforce the driving prohibition. FMCSA also

proposed several clarifying and conforming changes to current regulations.

B. Comments and Responses

FMCSA solicited comments on the NPRM for 60 days, through June 29, 2020. By that date, 32 comments were received from commenters representing 9 individual States (CA, IA, IL, MT, NE, NY, OR, TX, and VA), 9 entities, and 14 private citizens. The following entities submitted comments: AAMVA, American Trucking Associations (ATA), Driver iQ, Greyhound Lines, Inc. (Greyhound), National Motor Freight Traffic Association (NMFTA), National Student Transportation Association (NSTA), Owner-Operator Independent Drivers Association (OOIDA), Truckload Carriers Association (TCA), and the Alliance for Driver Safety & Security (Trucking Alliance).

Comments on the NPRM were mixed. Most commenters, including all States, supported the proposed non-issuance requirement. Most entities, several States, and some individuals supported the proposed mandatory downgrade (or other State enforcement action on the driver's license), while other States and AAMVA opposed it. Two commenters suggested alternative approaches to the mandatory downgrade. The majority of commenters addressing FMCSA's second proposed alternative, optional notice to States of a driver's prohibited status, opposed it. Several comments addressed drug and alcohol testing issues outside the scope of the rulemaking. The comments and the Agency's responses, organized by topic, are summarized below.

Non-Issuance

The NPRM proposed that States be prohibited from completing specified CDL/CLP transactions if the mandatory SDLA query to the Clearinghouse indicates the applicant is currently subject to the CMV driving prohibition in 49 CFR 382.501(a).

Comments: All commenters specifically addressing this proposal, including the nine State commenters, supported it, citing the benefit to public safety. The Commonwealth of Virginia, Department of Motor Vehicles (Virginia DMV) observed that ". . . SDLAs are the only entities that can enforce the driving prohibition through the licensing process." Similarly, the Iowa Department of Transportation (Iowa DOT) noted that non-issuance "would effectively close the DACH regulatory loopholes allowing drivers testing positive to avoid detection, continue holding a valid CDL, and evade the CMV driving prohibition." The Oregon

Department of Transportation, Driver and Motor Vehicle Services (Oregon DOT) said that it said that it agrees with FMCSA's interpretation that the intent of MAP-21 was "to deny issuance when an individual has adverse information in the Clearinghouse . . ." Driver iQ expressed a similar opinion regarding congressional intent. The ATA commented that non-issuance "is a necessary step to close the loophole in FMCSA's regulations that continues to allow prohibited drivers to operate," while TCA described the proposal as "commonsense."

FMCSA Response: The Agency acknowledges the commenters' broad support for this provision. We agree that non-issuance is an important next step in achieving MAP-21's goal of using Clearinghouse information to improve highway safety. As noted above in Section II. B., FMCSA retains the non-issuance requirements in the final rule, with one clarifying change, addressed below.

Renewal of the H Endorsement Subject to Non-Issuance

Comment: The Oregon DOT asked FMCSA to clarify whether a driver renewing a hazardous material endorsement under 49 CFR 383.141 is "subject to non-issuance when adverse information is present in the Clearinghouse."

FMCSA Response: Yes. Drivers transporting hazardous materials, as defined in 49 CFR 383.5, are subject to the CDL requirements of part 383 and, therefore, subject to FMCSA's drug and alcohol testing regulations. The hazardous material (H) endorsement is unique, however, in that it is the only endorsement subject to renewal, as required by 49 CFR 383.141(d). The initial issuance of the H endorsement would, therefore, be an upgrade, and the SDLA would query the Clearinghouse in accordance with 49 CFR 383.73(e)(8) prior to issuance. The renewal of the H endorsement falls within the SDLA's query requirement in 49 CFR 383.73(d)(9). If the driver is prohibited from operating a CMV, the SDLA must not renew the H endorsement, and must comply with the downgrade requirements in 49 CFR 383.73(q), as applicable. FMCSA clarifies the regulatory text of 49 CFR 383.73(d)(9) accordingly.

Mandatory Downgrade (Alternative #1)

Under the Agency's preferred proposed alternative ("Alternative #1"), SDLAs would be required to remove the CLP or CDL privilege from the driver's license after receiving electronic notification from FMCSA (by "push" or

“pull”) that the individual is prohibited from operating a CMV. Upon receiving notification, SDLAs would initiate State downgrade procedures, and must complete and record the downgrade on the CDLIS driver record within 30 days of receiving such notice.

Comments Supporting Alternative #1: Eight of the nine entities commenting on the NPRM supported the downgrade (or some other form of mandatory State action on the driver’s license), as did several States and individuals. The New York State Department of Motor Vehicles (NYSDMV) said that, under this alternative, “a uniform nationwide system will improve safety and consistency.” Greyhound also noted the benefit of a uniform approach, stating that “[a]s a nationwide carrier, Greyhound needs this uniformity.” The Virginia DMV, though concerned about FMCSA’s ability to efficiently implement the electronic notification process, nevertheless supported this alternative, stating that “[d]owngrading a credential allows for more avenues of enforcement that will ultimately take unsafe drivers off the road.” The State of Nebraska Department of Motor Vehicles (Nebraska DMV) supported the downgrade “at the time of issuance (*i.e.*, renewal, upgrade, adding/removing restrictions or transferring from another state),” but not otherwise, due to “complexities” associated with downgrading the license outside of the issuance process. The State of Texas Department of Public Safety (DPS), citing safety concerns posed by prohibited drivers, said that it favored State action on the driver’s license, but would prefer an enforcement action, such as revoking, suspending, or disqualifying the CDL, over a license downgrade. The NSTA expressed a similar preference. (*Note:* State-based enforcement actions on the driver’s license are discussed separately below, under the topic, *Meaning of the Term “CDL Downgrade”*.) Driver iQ said that, under Alternative #1, “the carrier is far more likely to become aware of this downgrade either through established employer notification systems, the required annual motor vehicle record review required under 49 CFR 391.25(a), or via a roadside inspection, and remove the driver from the safety sensitive function.” The NMFTA noted that, in addition to the safety benefits of Alternative #1, it would also reduce motor carriers’ exposure to liability. An individual said the downgrade “will give [CMV drivers] more incentive to not do drugs or drink and drive.” The ATA observed that failing to require the downgrade would allow “some states to

ignore readily available safety information,” while requiring the downgrade “would provide a level of assurance to motor carriers and the motoring public that individuals who maintain a valid CLP/CDL are both safe and qualified.” OOIDA recognized that Alternative #1 “would ensure that drivers with legitimate drug and alcohol violations are not able to operate CMVs until they have satisfied return-to-duty protocols.”

FMCSA Response: The Agency agrees with comments recognizing the safety benefits of the proposed mandatory downgrade. As explained in the NPRM, FMCSA prefers this alternative because it uses driver-specific Clearinghouse information to increase compliance with the CMV driving prohibition, consistent with the purpose of MAP–21, as set forth in 49 U.S.C. 31306a(a)(2)(A) and (B). The downgrade requirement, retained in the final rule, will accomplish this objective in a uniform and effective way by ensuring that CMV drivers subject to the prohibition in 49 CFR 382.501(a) do not hold a valid CLP or CDL.

Comments Opposing Alternative #1: The States of CA, IA, IL, MT, and OR opposed the mandatory downgrade, as did AAMVA and several individual commenters. As noted above, Nebraska DMV believed that the downgrade should be required only during the CLP/CDL issuance process. Commenters based their opposition on various implementation and policy concerns, which are addressed separately by topic, below.

Proposed 30-Day Time Window for Completing the Downgrade

In the NPRM, FMCSA asked whether the proposed 30-day timeline for completing the downgrade allowed SDLAs sufficient time to comply with State-based procedural due process requirements. FMCSA noted its intention, when notifying drivers that a violation has been reported to the Clearinghouse, to also inform them that their State of licensure has been notified and must downgrade the driver’s license within 30 days. FMCSA asked whether its notification of drivers would satisfy existing State-based notice requirements, thereby relieving States of this administrative burden.

Comments: Most SDLAs confirmed that, even if FMCSA notified the driver of an impending downgrade, they would still be required to notify the driver directly, as required by State law. Two State commenters noted the proposed 30-day time frame would not allow sufficient time for the SDLA to comply with these requirements, which

include notifying the driver of the pending license action (*e.g.*, downgrade) and, in some cases, providing opportunity for an administrative hearing prior to completing the action. One State said the time period should be consistent with the medical certification downgrade process, which allows the State 60 days to downgrade the license and update the CDLIS driver record. ATA and NMFTA commented that 30 days is sufficient and expressed concern that extending the time frame beyond 30 days would adversely impact highway safety.

Other commenters were concerned that drivers would complete RTD well within the 30-day window, rendering the downgrade procedures meaningless. The Office of the Illinois Secretary of State (Illinois) said that “[w]e do not feel downgrading the driver is the best action because they may be cleared to return to service by the time the downgrade is completed.” AAMVA and several State commenters suggested that FMCSA withhold the push notification to the SDLA for 30 days, which would give drivers an opportunity to avert a licensing action by quickly completing RTD, and would allow SDLAs to avoid the administrative burden of providing procedural due process for such drivers. In support of this approach, commenters pointed to FMCSA’s estimate, discussed in the NPRM, that 82 percent of drivers choosing to complete the RTD process would do so before the SDLA records the downgrade.¹³ The Iowa DOT noted that, based on FMCSA’s estimate, some individuals could conceivably complete RTD before receiving the initial downgrade notice from the SDLA, resulting in confusion for drivers, and the SDLA’s need to hire additional staff to address drivers’ questions. The Oregon DOT commented that a “waiting period” of 15 to 30 days before FMCSA notifies the SDLA of a driver’s status “would remove the burden on States to notify individuals who go on to resolve their § 382.501(a) CMV driving prohibition” within the waiting period.

FMCSA response: FMCSA accepts the SDLAs’ explanation that they must abide by the driver notification requirements in their respective States, even if FMCSA notifies the driver that

¹³ See 85 FR 23670, 23688. As discussed in the NPRM, this estimate is based on: (1) The assumption, as stated in the Regulatory Impact Analysis for the Clearinghouse final rule, that 75 percent of drivers violating FMCSA’s drug and alcohol program would be referred to a 16-hour education program that can be completed well within 30 days; and (2) a 2018 report, issued by HHS’ Substance Abuse and Mental Health Services Administration, indicating that 82 percent of individuals receiving substance abuse treatment participated in outpatient education programs.

his or her license is subject to downgrade. The Agency also acknowledges that 30 days would not provide some SDLAs enough time to accommodate applicable due process requirements. FMCSA, therefore, extends the time frame for completing the downgrade from 30 days, as proposed, to 60 days, in this final rule. FMCSA notes the 60-day time window aligns with current medical certification downgrade requirements in 49 CFR 383.73(o)(4). The Agency acknowledges the concern that extending the period beyond 30 days could negatively impact safety. In response, FMCSA notes that SDLAs may complete and record the downgrade sooner than 60 days, if their State processes allow. FMCSA encourages SDLAs to complete the downgrade as soon as possible, as permitted by State law.

FMCSA does not agree with the suggestion to withhold notification to SDLAs of the driver's prohibited status for up to 30 days, to allow States to avoid downgrade-related administrative costs for drivers who timely complete RTD. The Agency emphasizes that CMV drivers who engage in the prohibited use of drugs or alcohol pose an immediate risk to public safety, and it would be irresponsible for FMCSA to withhold that information from SDLAs. As noted in the NPRM, the prohibition in 49 CFR 382.501(a) takes effect as soon as the drug and alcohol program violation occurs. Moreover, FMCSA's estimate that 82 percent of drivers completing RTD will do so within 30 days, as set forth in the NPRM, must be viewed in context. The NPRM, citing the Regulatory Impact Analysis (RIA) of the 2016 Clearinghouse final rule, also estimated that 45 percent of drivers who test positive elect to consult with an SAP and begin the RTD process.¹⁴ The remaining 55 percent presumably leave the industry, voluntarily give up their CDL to drive CMVs not requiring a commercial license, or continue to operate in violation of the driving prohibition. Given that the majority of drivers who test positive do not complete RTD, FMCSA's withholding notice of prohibited status from SDLAs, for any length of time, would be contrary to public safety. (The Agency's estimate of the number of drivers who will complete RTD is discussed further

below, in Section XI., Regulatory Analyses.)

Procedural/Due Process Concerns

Comments: The Nebraska DMV commented that downgrading the license outside the issuance process, which would be "the result of [FMCSA's] request," raises procedural questions. Specifically, Nebraska DMV asked: ". . . who the driver is supposed contact with questions; Who sends the driver the downgrade letter? How will we know when the driver's issue is resolved with FMCSA? If FMCSA sends the letter, but the SDLA is responsible for the CDLIS record, what happens if FMCSA doesn't send the letter in a timely manner or at all?" AAMVA asked whether the surrender of a CLP or CDL would be required as part of the proposed downgrade. The Virginia DMV, though supporting the downgrade, expressed concern "with conducting hearings for individuals contesting the downgrade of their credential." The Virginia DMV noted that it would have no evidence to justify the downgrade "other than the notification based on the report of an employer received from the Clearinghouse."

FMCSA Response: As discussed above, State laws determine whether the SDLA must notify a driver of the impending downgrade, and, if so, how and when that would be accomplished. Drivers with questions about their specific licensing status, including how they can reinstate the CLP or CDL if a downgrade occurs, will need to contact the SDLA that issued the license. Drivers with questions about their Clearinghouse record, the impact of a violation on their CMV operating status, or what the Federal regulations require the SDLAs to do once notified of a driver's prohibited status, may contact FMCSA through the Clearinghouse website (<https://clearinghouse.fmcsa.dot.gov/>). As explained in the NPRM, State downgrade processes will be initiated when FMCSA notifies the SDLA, through CDLIS or other electronic means, of a driver's prohibited status. The Agency will also notify the SDLA when the driver, having complied with RTD requirements, is no longer prohibited from operating a CMV. FMCSA's first notification to the SDLA will occur when a driver's employer, or the employer's service agent (*i.e.*, medical review officer, consortium/third party administrator), reports a violation to the Clearinghouse. The second notice will occur when a driver's negative RTD test result is reported to the Clearinghouse.

The final rule retains these notification requirements, as proposed.

As noted in the NPRM, FMCSA, when notifying drivers of a reported violation, as required by 49 CFR 382.707(a), intends to also let drivers know their SDLA has been informed of their prohibited status, and is required to initiate a downgrade of their license. If the driver is registered in the Clearinghouse, FMCSA will notify the driver via email; otherwise, drivers will receive notification by U.S. mail. The purpose of this notice is simply to further clarify the process for drivers and let them know what to expect. In response to AAMVA's question about surrender of the CLP or CDL, the Agency notes that States will rely on their established procedures to remove the CLP or CDL privilege from the driver's license. Whether a physical surrender of the credential is required as part of that process will, therefore, be determined by the State.

In response to the Virginia DMV's comment, the Agency notes that each State maintains its own due process requirements. It is, therefore, entirely within the States' discretion to determine whether CMV drivers may contest a downgrade or other pending license action. The evidentiary standards and burden of proof applicable in such proceedings would be determined on a State-by-State basis.

Downgrade for Issuance of Citation for DUI

Comment: The Iowa DOT opposed Alternative #1 because it "would require us to initiate a commercial downgrade after receiving an OWI and prior to receiving an OWI conviction," which would create confusion and cause delays to existing processes. (In Iowa, 'operating while intoxicated,' or OWI, is the equivalent of DUI.) The Iowa DOT takes action only when the driver refuses or fails an OWI test, or is criminally convicted of OWI. In that situation, the Iowa DOT revokes "a person's base driving privilege, which thereby disqualifies their commercial driving privileges."

FMCSA Response: Currently, if a motor carrier employer knows that a driver it employs has received a citation for DUI in a CMV, the employer has "actual knowledge" of the employee's prohibited use of drugs or alcohol, as defined in 49 CFR 382.107. The employer's report of actual knowledge of prohibited use ("actual knowledge violation"), based on the issuance of a citation for DUI in a CMV, must be reported to the Clearinghouse, as required by 49 CFR 382.705(b)(4). (This issue is discussed further below under

¹⁴ The NPRM cited the 2016 Clearinghouse final rule RIA's estimate that 53,500 drivers would test positive and be required to complete RTD before resuming safety-sensitive functions, including operating a CMV. Of these, 24,000 drivers (45 percent) would complete RTD. See 85 FR 23670, 23688.

the topic heading, “*Actual Knowledge Violations Based on Issuance of Citation for DUI in a CMV.*”) FMCSA notes that, after the employer reports the actual knowledge violation to the Clearinghouse, the SDLA will receive notice only of the driver’s prohibited status, and will not be aware of the driver’s specific drug or alcohol violation (*i.e.*, positive test result, test refusal, or the employer’s actual knowledge of prohibited use of drugs or alcohol). The downgrade is therefore triggered by the actual knowledge violation reported to the Clearinghouse by the employer, rather than the DUI citation itself.

FMCSA notes, however, that drivers prohibited from operating a CMV under 49 CFR 382.501(a) face separate, and more severe, consequences if they are ultimately convicted of DUI in a CMV. If a driver is convicted of that offense, he/she would be disqualified from operating a CMV for a minimum of 1 year, in accordance with 49 CFR 383.51(b)(1) or (2).

Necessity of Downgrade

Comments: The Montana Department of Justice, Motor Vehicle Division (MDOJ–MVD) commented that the downgrade is unnecessary since a driver’s prohibited operating status is accessible to roadside enforcement officers through Nlets.¹⁵ Similarly, the Iowa DOT noted that roadside detection of the driver’s prohibited status through the “CDLIS Central Site” would preclude the need for SDLA involvement. AAMVA commented that, instead of a downgrade, “direct law enforcement access to DACH data could more appropriately accomplish the goal of enforcing against prohibited drivers.” The Oregon DOT believed that CDLIS is “not an appropriate location to attempt to represent adverse Clearinghouse data,” and suggested that “FMCSA may instead wish to provide for enhanced capabilities for law enforcement to view an individual’s status in the Clearinghouse during roadside stops.”

FMCSA Response: A license downgrade and roadside access to a driver’s prohibited status are not mutually exclusive; each provides a separate basis for enforcement intervention. As explained in the NPRM (85 FR 23670, 23682) and above in

Section II. B., MCSAP officers’ roadside access to the driver’s prohibited status (determined before the downgrade takes effect and the CLP/CDL is still valid), will enable enforcement of the driving prohibition under 49 CFR 392.15. However, some non-MCSAP State and local traffic safety officers would be unaware of the driver’s prohibited status during the period before the downgrade is completed because, unlike MCSAP personnel, they lack reliable roadside access to FMCSA’s enforcement data through *cdlis.dot.gov* or Query Central (the driver’s DACH status is not currently accessible through Nlets). The downgrade of a CMV driver’s license will allow these State and local traffic safety officers to determine the driver is not legally authorized to operate a CMV by conducting a routine license check. If the SDLA has completed the downgrade at the time the check is conducted, the officer will know the driver does not hold a valid CLP or CDL, thereby providing a basis for enforcement action in accordance with 49 CFR 391.11(b)(5). In the absence of a license downgrade, some of these officers would be unaware of the driver’s prohibited status because, unlike MCSAP personnel, they lack reliable roadside access to FMCSA’s enforcement data through *cdlis.dot.gov*. Non-MCSAP officers will, however, be able to detect prohibited drivers by conducting a routine license check, if the SDLA has completed the downgrade at the time the check is conducted. The downgrade will therefore strengthen roadside enforcement of the CMV driving prohibition by allowing all traffic safety personnel to be aware that the prohibited driver is not licensed to operate a CMV. Further, the downgrade, by increasing the consequences of non-compliance for CMV drivers, provides an incentive for drivers to complete RTD to restore their commercial driving privileges. The Agency believes it may also deter the prohibited use of drugs and alcohol.

FMCSA’s Legal Authority/Congressional Intent

Comments: The MDOJ–MVD questioned whether “federal law authorizes FMCSA to regulate SDLAs to downgrade CLP/CDL outside of issuance transactions.” AAMVA maintained that congressional intent underlying the State-specific Clearinghouse statutory requirements is “less clear than FMCSA concludes.” AAMVA further asserted that, “[c]ontrary to FMCSA’s proposal in this NPRM, there is no legal basis for a state to downgrade, not issue, or otherwise take a state licensing action for a driver

refusal or failure of a drug or alcohol test.”

FMCSA Response: The Agency’s legal authority to issue the final rule is explained above in Section IV., Legal Basis for the Rulemaking (and was set forth in the Legal Basis section of the NPRM). As noted therein, in addition to MAP–21, FMCSA relies on the concurrent statutory authority of 49 U.S.C. chapter 313, which establishes the Agency’s jurisdiction to set minimum standards for the issuance of CLPs and CDLs and the fitness of CMV operators. As discussed in Section V.A., FMCSA relies on the authority of 49 U.S.C. 31308 and 31305(a) to adopt the downgrade requirement in this final rule. The Agency notes that the downgrade requirement is also consistent with the MAP–21 requirements in 49 U.S.C. 31311(a)(24) and 49 U.S.C. 31306a(h)(2).

Suggested Alternatives to Proposed Mandatory Downgrade

Comments: In lieu of a downgrade, an individual commenter suggested that SDLAs issue a “temporary CDL,” valid for 30–60 days, which would provide time for drivers to resolve the issue while still driving legally; “[t]he fact that it is a temporary CDL and the reason why would be shown on their MVR.” The Iowa DOT said that a better way to ensure effective enforcement of the driving prohibition would be the adoption of uniform standards for disqualification when a CLP or CDL holder “has a certain number or severity of violations under the drug and alcohol program,” for example, “a certain number of positive test results within an established time frame results in a 30-day disqualification.” AAMVA stated that “FMCSA must make a determination on whether the driver is disqualified and notify the licensing authority accordingly.”

FMCSA Response: As noted above, the CMV driving prohibition in 49 CFR 382.501(a) takes effect at the time the driver engages in conduct violating FMCSA’s drug and alcohol program. The issuance of a temporary CDL allowing the driver to operate after a violation occurs would be contrary to the prohibition and poses an obvious risk to public safety. As explained in the NPRM, CLP and CDL holders subject to the downgrade are not “disqualified” under 49 CFR part 383.¹⁶ Each of the driver disqualifications required under part 383 is specifically set forth in statute (49 U.S.C. 31310). Driver disqualifications under 49 CFR 383.51 require that the individual be convicted

¹⁵ Nlets, formerly the National Law Enforcement Telecommunications System, is now operating as the Nlets-International Justice and Public Safety Network. Its mission is to facilitate the electronic exchange of public-safety information, including motor vehicle and drivers’ data, among State law enforcement agencies, Federal agencies with a justice component, and other strategic partners serving the law enforcement community.

¹⁶ 85 FR 23670, 23678.

of a specified traffic violation, while drivers are disqualified under § 383.52 only if they are determined to constitute an imminent hazard, as defined in § 383.5. While drug and alcohol program violations raise obvious safety concerns, drivers subject to the CMV driving prohibition do not meet either of these disqualification criteria. Moreover, under the drug and alcohol program requirements set forth in 49 CFR parts 40 and 382, a driver is eligible to resume safety-sensitive functions following completion of RTD requirements. The purpose of the RTD requirements is rehabilitative, not punitive. FMCSA believes that disqualifying drivers for a pre-determined period of time, regardless of their RTD status, is inconsistent with this principle.

Meaning of the Term “CDL Downgrade”

The NPRM proposed that, for individuals subject to the CMV driving prohibition, SDLAs downgrade the driver’s license (*i.e.*, remove the commercial driving privilege) by changing the commercial status on the CDLIS driver record from “licensed” to “eligible” for CDL holders, and changing the permit status from “licensed” to “eligible” for CLP holders. These designations, currently set forth in the AAMVA CDLIS State Procedures Manual¹⁷ (AAMVA CDLIS Manual), describe how the State currently records the downgrade on the CDLIS driver record of individuals whose medical certification status changes from “certified” to “not certified,” as required by 49 CFR 383.73(o)(4). In order to further clarify the meaning of the term *downgrade*, as used in the NPRM, FMCSA proposed to amend the current definition of *CDL downgrade*, set forth in 49 CFR 383.5, and to add a new definition of *CLP downgrade*, incorporating the AAMVA CDLIS Manual procedures described above.

Comments: As noted previously, both the Texas DPS and the NSTA stated their preference for enforcement action on the license, such as suspension, revocation, or cancellation of the CDL, over a downgrade. Texas noted that “[t]he act of downgrading a CMV driver does not have the same impact as suspending, revoking, or disqualifying the CDL,” and that an enforcement action, recorded in the driver history, “would allow for proper tracking and enforcement roadside.” The NSTA said that a downgrade “results in additional steps for the SDLAs, and leaves room for

error as a result.” AAMVA urged FMCSA to clarify what is to appear on the driver record, observing that “[S]tates should not be left to interpret what the [prohibited] designation means in terms of eligibility.”

FMCSA Response: As set forth in 49 CFR 383.5, the term *CDL downgrade* means, among other things, the State’s removal of the CDL privilege from the driver’s license. In the NPRM, FMCSA intended to clarify how SDLAs would accomplish the downgrade by proposing that AAMVA’s CDLIS procedures, described above, be incorporated into the regulatory definition of downgrade. We did not, however, intend to convey that changing the commercial license or permit status from “licensed” to “eligible” would be the only action States could take to remove the CLP or CDL privilege from the driver’s license. Accordingly, to avoid confusion on this issue, FMCSA does not incorporate the proposed definitions of *CDL downgrade* and *CLP downgrade* in the regulatory text of this final rule. (The final rule does, however, clarify that the term *CDL downgrade* also includes the removal of the CLP privilege.)

As explained in the NPRM, and discussed above in Section V.C., *Impact of MAP–21 on State Laws*, MAP–21 exempts from Federal preemption State licensing actions relating to a driver’s CDL, or driving record, due to violations of FMCSA’s drug and alcohol program.¹⁸ The final rule requires that the SDLA downgrade the driver’s license of CLP or CDL holders who are subject to the CMV driving prohibition, as proposed; this is a minimum requirement. FMCSA anticipates that States will record the downgrade by changing the commercial status on the CDLIS driver record from “licensed” to “eligible,” consistent with current practice for medical certification downgrades required by 49 CFR 383.73(o)(4).¹⁹ The Agency notes that States may, at their discretion, suspend, revoke, cancel, or otherwise remove the CLP or CDL from the license, relying on existing State procedures to record the action on the CDLIS driver record. In the Agency’s judgment, this approach is consistent with the preemption exception in MAP–21, discussed above,

¹⁸ 82 FR 23670, 23679–23680. MAP–21 exempts from Federal preemption State requirements relating to “an action taken with respect to a commercial motor vehicle operator’s commercial driving license or driving record” due to a verified positive test result, a test refusal, or other violations of 49 CFR part 382, subpart B (49 U.S.C. 31306a(l)(3)).

¹⁹ AAMVA CDLIS State Procedures Manual, Release 5.3.3 (Dec. 2015), at 95; AAMVA CDLIS Technical Specifications Manual, Release 5.3.3 (Dec. 2015), at pp. 669–70; 683.

while also maintaining a uniform outcome across the country, *i.e.*, the States’ removal of the commercial driving privilege from the driver’s license of CMV operators subject to the prohibition. Regardless of how the State removes the commercial privilege, the CDLIS driver record must show that the driver does not hold a valid CLP or CDL. The State must record the downgrade, or other discretionary licensing action, on the CDLIS driver record within 60 days of receiving notice of the driver’s prohibited status.

Integration of Clearinghouse and Medical Fitness Requirements

Comments: AAMVA observed that the Agency’s citation of 49 U.S.C. 31305(a), which requires the Secretary to prescribe minimum standards for testing and fitness of CMV drivers, “implies that [Clearinghouse] program requirements are directly linked to medical fitness requirements rather than any new or additional requirements.” AAMVA further stated: “. . . from a policy standpoint, if drug and alcohol testing failures are to be comprehensively considered as part of ‘medical fitness’ it seems those programs should also be contracted as a single, comprehensive source for making medical fitness determinations by external entities (including SDLAs)” (emphasis in original).

FMCSA Response: Because *fitness*,²⁰ as the term is used in 49 U.S.C. 31305(a), is not defined in statute, FMCSA interprets the term according to its plain meaning. For example, the Oxford Dictionary defines *fitness* as, alternatively, “the condition of being physically fit and healthy,” or “the quality of being suitable to fulfill a particular role or task.” The Agency’s reference to 49 U.S.C. 31305(a) simply reflects that CLP or CDL holders or applicants who are subject to the prohibition in 49 CFR 382.501(a) are not “fit” to operate a CMV. FMCSA did not, therefore, intend to imply a “direct link” between its drug and alcohol program requirements in 49 CFR part 382 and medical certification requirements in 49 CFR part 391, subpart E. The two sets of regulatory requirements each have distinct purposes and underlying statutory authorities. These programs have always been administered separately, and the NPRM did not propose to change that.

²⁰ The Oxford Dictionary, available at <https://www.lexico.com/definition/fitness> (accessed Jan. 14, 2021).

¹⁷ AAMVA CDLIS Procedures Manual, Release 5.3.3 (Dec. 2015), at 95; AAMVA CDLIS Technical Specifications Manual, Release 5.3.3 (Dec. 2015), at pp. 669–70, 683.

Downgrades Based on Incorrect Clearinghouse Information

As noted in the NPRM, if violation information reported to the Clearinghouse is subsequently determined to be incorrect, or fails to meet reporting requirements, it may be removed from the Clearinghouse in accordance with 49 CFR 382.717, or DOT's Privacy Act regulations in 49 CFR part 10. FMCSA proposed that, if a driver's license is downgraded as the result of incorrect Clearinghouse information, the SDLA should reinstate the commercial privilege, and update the driving record, "as fairly and efficiently as possible" following notification from the Agency that the driver is not prohibited from operating a CMV. We requested comment from SDLAs and drivers on whether FMCSA should include corrective action procedures in the final rule, or whether States should rely on their own processes to address this issue.

Comments: The seven State commenters addressing this question all preferred that the SDLAs rely on existing State procedures to correct errors on an individual's license or driving record, once notified by FMCSA. AAMVA commented that FMCSA should not mandate how the reinstatement should occur since SDLAs have existing correction procedures, but that "FMCSA should be the sole party responsible for correcting erroneous information contained in the DACH. . . ." The Agency received no driver comments in response to this question.

FMCSA Response: The final rule does not establish specific procedures for States' reinstatement of the CDL or CLP to the driver's license, or correction of the driving record, following FMCSA's notification that a Clearinghouse error occurred. It does, however, require the SDLA to reinstate the commercial privilege, and expunge the driving record, following error correction. As explained in the NPRM, FMCSA is responsible for ensuring the accuracy of information in a driver's Clearinghouse record, and for informing the SDLA when an error affecting a driver's licensing status is discovered. Accordingly, the Agency will promptly notify the SDLA that the driver's prohibited status, previously reported to the SDLA, was based on erroneous Clearinghouse information, and the driver is not prohibited from operating a CMV. If the State has completed the downgrade (or other discretionary licensing action) at that point, it must expeditiously reinstate the commercial privilege to the driver's license, and

correct the driving record,²¹ in accordance with established State procedures. FMCSA believes these requirements will mitigate, to the extent possible, the impact of State licensing actions on drivers based on erroneous Clearinghouse information.

The Agency notes that reinstatement following error correction is distinct from the "regular" reinstatement process proposed in the NPRM. In that scenario, the driver's drug and alcohol program violation is reported to the Clearinghouse; the SDLA initiates a downgrade of the driver's license following notification from FMCSA of the driver's prohibited status; and, following the driver's completion of RTD requirements, the SDLA receives notification that the driver is no longer prohibited from operating a CMV. At that point, the driver would be eligible for reinstatement of the CLP or CDL, as permitted by State law. The final rule retains this reinstatement provision, essentially as proposed (49 CFR 383.73(q)(2)).

Optional Notice of Prohibited Status (Alternative #2)

This proposed alternative would permit, but not require, SDLAs to receive "push" notifications of a driver's prohibited status. States would determine whether, and how, to use the information to improve compliance with the CMV driving prohibition.

Comments: AAMVA and the MDOJ-MVD preferred this alternative over the mandatory downgrade, citing the flexibility it affords to States. Other commenters expressed concern about the lack of uniformity inherent in this approach. The Iowa DOT opposed the adoption of Alternative #2, stating that it "will create inconsistent consequences for a driver's drug and alcohol program violation, and therefore, create confusion and complaints among drivers and carriers." Driver iQ said that this approach "would allow States to abdicate their responsibility for highway safety by ignoring risk and/or failing to act." The NMFTA noted that Alternative #2 would result in "a complicated and confused regulatory framework" in which "drivers and carriers operating in states with less stringent CDL and [CLP] checks would have a competitive advantage over others operating under stricter rulesets."

FMCSA Response: The Agency agrees with commenters noting the drawbacks

²¹ In this context, the term *driving record* includes the CDLIS driver record, as defined in 49 CFR 383.5, and the *Motor vehicle record*, as defined in 49 CFR 390.5, if applicable.

of the State-by-State approach envisioned under Alternative #2. As discussed above, the final rule does not adopt this alternative.

Inclusion of CLP Holders in State Query

The proposed inclusion of CLP holders in the States' mandatory query was intended to correct an oversight in the Clearinghouse final rule, as the query requirement is currently limited to CDL holders.

Comments: AAMVA noted that "until an applicant is issued a CLP, they would not have a corresponding record in the DACH, making this process irrelevant in some cases."

FMCSA Response: The Agency acknowledges that CLP applicants who have no prior commercial license history will not have a Clearinghouse record. However, the query is necessary because some CLP applicants may have previously held a CLP or CDL issued by another State. The final rule requires, as proposed, that States query the Clearinghouse prior to issuing, renewing, or upgrading a CLP.

Addition of CMV Driving Prohibition to 49 CFR Part 392

FMCSA proposed to add the prohibition, set forth in 49 CFR 382.501(a), to part 392, to further assist the States' enforcement of the prohibition in connection with CMV traffic stops, inspections, and other roadside interventions.

Comments: Driver iQ supported this proposal, noting that "all state law enforcement should be authorized to hold drivers accountable at roadside." AAMVA asked for confirmation that the "FMCSA views the new prohibition incorporated into § 392.15 as a 'disqualification' for purposes of performing a CDLIS record check [as required by § 384.205]."

FMCSA Response: As explained in the NPRM, the purpose of adding the prohibition to part 392 is to assist in the States' roadside enforcement during the period in which a driver, who is prohibited, nevertheless holds a valid CLP or CDL because the commercial privilege has not yet been removed from the driver's license. The provision is therefore adopted as proposed. This provision does not render the prohibited driver "disqualified" for purposes of the CDLIS check required in 49 CFR 384.205. In the NPRM, FMCSA noted that, if the SDLA "pulled" driver-specific information from the Clearinghouse using the existing CDLIS platform, the driver's status would be provided as part of the CDLIS check already required under 49 CFR 384.205. The point was merely that using the

CDLIS platform would make a separate SDLA query to the Clearinghouse unnecessary. Adding the prohibition to part 392 is entirely unrelated to the SDLAs' CDLIS check, and the NPRM did not suggest any connection between the two.

Actual Knowledge Violations Based on Issuance of Citation for DUI in a CMV

Under 49 CFR 382.107, employers have "actual knowledge" of a driver's prohibited drug or alcohol use if they are aware that the driver was issued a traffic citation for DUI in a CMV; under the 2016 Clearinghouse final rule, the actual knowledge violations must be reported to the Clearinghouse. Drivers who are not convicted of the offense may petition to have the actual knowledge violation removed from their Clearinghouse record. The NPRM clarified that under current regulations, when a CLP or CDL holder is cited for DUI in a CMV, the driver has engaged in conduct prohibited by 49 CFR part 382, subpart B, regardless of whether the driver is ultimately convicted of the offense. FMCSA proposed, therefore, that reports of actual knowledge based on the issuance of a traffic citation for DUI in a CMV should remain in the Clearinghouse for 5 years, regardless of whether the driver is convicted; drivers not convicted of the offense could add evidence of non-conviction to their Clearinghouse record so that future prospective employers would be aware that the driver, though charged with DUI in a CMV, was not convicted of the offense.

Comments: The ATA supported the proposed revision, commenting that it would "ensure compliance with the Clearinghouse's statutory requirements to include all DOT alcohol and drug violations while providing fairness to drivers and full disclosure to employers." The Trucking Alliance was also in favor of the change, noting that "[c]onviction of a traffic citation is a separate issue and carries different consequences." There were no comments opposing the proposed revision.

FMCSA Response: As proposed, the final rule requires that actual knowledge violations based on this issuance of a traffic citation²² for DUI in a CMV remain in the Clearinghouse for 5 years, commensurate with other drug and alcohol prohibitions identified in 49

CFR part 382, subpart B.²³ Drivers may submit documentary evidence of non-conviction to their Clearinghouse record, which will ensure future prospective employers who conduct pre-employment queries on the driver will be aware that the driver was not convicted of DUI in a CMV by viewing his/her Clearinghouse record.

Proposed Change to 49 CFR 382.503—Resumption of Safety-Sensitive Functions

This section currently provides that a driver who has engaged in conduct prohibited by 49 CFR part 382, subpart B, must not perform safety-sensitive functions, including operating a CMV, until completing RTD requirements. Under Alternative #1, the NPRM proposed to clarify this provision by stating that a driver whose CLP or CDL was downgraded, in accordance with 49 CFR 383.73(q), could not resume driving a CMV until the State restored the commercial driving privilege to the driver's license.

Comment: AAMVA interpreted the proposed change "to mean that a driver may only resume driving operations once the driver record transaction has been completed by the SDLAs," and noted that "the possible conflict in timing of clearance creates an inequity for drivers that is inconsistent with Clearinghouse law."

FMCSA Response: AAMVA correctly interprets the proposed change, which is adopted in this final rule. As discussed in the NPRM, FMCSA is aware that processes for reinstating the CLP/CDL privilege following a downgrade vary among the States. Depending on applicable State procedures, a gap may exist between the time the SDLA receives notification that the driver is no longer prohibited from operating a CMV, and the time the SDLA restores the CLP or CDL to the driver's license. The amendment to 49 CFR 382.503, by implicitly recognizing this possibility, is intended to clarify that an individual may not resume driving a CMV until fully licensed to do so. In the NPRM, FMCSA acknowledged that drivers and their employers may incur modest opportunity costs during this "gap" period and estimated what those costs would be. (The Agency's estimates of motor carrier and driver opportunity costs related to reinstatement following completion of RTD are discussed further below in Section XI.)

²³ 49 U.S.C. 31306a(g)(6)(A) requires that violations be retained in the Clearinghouse for 5 years; this requirement is set forth in 49 CFR 382.719(a)(4).

Transmission of Clearinghouse Information to the SDLAs

FMCSA proposed two alternatives for the electronic transmission of the driver's CMV operating status (prohibited or not prohibited) to SDLAs: (1) The existing CDLIS platform; or (2) a web-based service call, which would require an electronic interface between the SDLA and the Clearinghouse. We invited comment on the alternatives, and asked whether States should have the option to determine which method of electronic transmission would best suit their existing IT infrastructure.

Comments: Some State commenters addressing this question preferred the CDLIS platform, while others were unsure which option would be more efficient. The NYSDMV opposed "shifting to a web-based system when CDLIS is an established working system that meets all our needs." The Virginia DMV commented that CDLIS would be a more efficient and cost-effective alternative, noting that "SDLAs already use CDLIS to obtain other information during licensing transactions." The Nebraska DMV strongly preferred using "the existing CDLIS platform for electronic transmission of Clearinghouse information during time of issuance." Illinois said that CDLIS is currently the most efficient option but noted that they "are in the process of system modernization so this may change to web based by the time this program is implemented." AAMVA recommended that "the final rule be developed in such a way that the technology solution is not prescriptive and affords states maximum flexibility in complying with regulatory requirements."

FMCSA Response: The comments reflect that States have varying IT system capabilities and resources. The Agency, therefore, does not establish a specific method of electronic transmission in the final rule. As AAMVA noted, a non-prescriptive IT requirement will allow each SDLA the flexibility to determine the IT solution that is the best fit for them. FMCSA will work closely with AAMVA and the States in developing system specifications that will accommodate the States' use of the CDLIS platform, as well as web-based alternatives, to request and receive information from the Clearinghouse.

Compliance Date

FMCSA requested comment on how long it would take States to implement changes to their IT systems that would enable them to electronically request and receive Clearinghouse information,

²² In 2019, the Agency amended 49 CFR 382.107 to clarify that *traffic citation*, as the term is used in the definition of *actual knowledge* in § 382.107, means "a ticket, complaint, or other document charging driving a CMV while under the influence of alcohol or controlled substances." See 84 FR 51427, 51428 (Sept. 30, 2019).

once FMCSA makes the technical specifications available.²⁴

Comments: State responses to this question varied, ranging from 18 months to 4 years following FMCSA's development of technical specifications. The Virginia DMV also pointed out that simultaneous implementation of the electronic initiatives associated with the National Registry of Certified Medical Examiners (NRCME), the Training Provider Registry (TPR), and the Clearinghouse, would place an intolerable burden on the SDLAs. State commenters also noted the need to obtain State legislative authority to take licensing actions based on Clearinghouse information. AAMVA explained that "the time frame needs to account for legislative changes that may span multiple sessions, or be applicable to State legislatures that do not meet annually."

FMCSA Response: FMCSA concludes that, in order to achieve full implementation of the State requirements set forth in the final rule, a 3-year compliance date is necessary. The Agency believes a 3-year period allows FMCSA sufficient time to develop the technical specifications States will need to modify their IT systems, and for States to implement those system changes. This time frame will also accommodate the SDLAs' need to obtain necessary legislative and fiscal authority from their respective States. In response to the Virginia DMV's concern about the "intolerable burden" of simultaneously implementing this final rule, along with the TPR and NRCME initiatives, FMCSA notes that implementation of the TPR (and other provisions of the Entry-Level Driver Training final rule) is on schedule to meet the compliance date of February 7, 2022. FMCSA recently extended the date by which States must comply with the medical examiners certification integration requirements, from June 22, 2021 to June 23, 2025. FMCSA is committed to providing States with the technical specifications underlying both the NRCME and DACH initiatives as soon as possible, so that States will have ample time complete the necessary modifications to their IT systems. (As noted above, in accordance with 49 CFR 350.303(b), FMCSA also adopts a 3-year compliance date for the requirements in 49 CFR 390.3, 390.3T, and 392.15 as set forth in this final rule.)

Costs

In the NPRM, FMCSA estimated cost impacts of the proposal, including CLP/CDL reinstatement costs and opportunity costs for drivers whose licenses are downgraded, opportunity costs for carriers that employ downgraded drivers, and SDLA costs related to IT modifications. In estimating SDLA costs, the Agency included IT system development and annual expenses for operations and maintenance for each proposed method of electronic transmission, as well as each of the proposed regulatory alternatives (downgrade; optional notice of prohibited status). FMCSA requested comment on the estimated costs and asked whether there are other costs to SDLAs that the Agency should consider.

Comments: State commenters identified various cost impacts not addressed in the NPRM, including: processing driver reinstatements, notifying drivers of a pending downgrade, training SDLA personnel, updating training materials, hiring additional personnel to process the downgrade and respond to customer questions and complaints, and updating SDLA websites to provide links and other information about the impact of the final rule on State licensing processes. AAMVA noted that "[e]ven with reliance on existing downgrade procedures, the cost associated with ongoing record maintenance and fulfilling the additional volume of data transactions on the record represent additional labor hours, IT resources, and systems testing," and provided qualitative cost information for each of the proposed methods for electronic transmission. In addition, AAMVA indicated CDLIS system modifications would be necessary. As noted above, FMCSA did not receive comments specifically addressing the estimated costs to drivers and motor carriers.

FMCSA Response: FMCSA acknowledges the information that AAMVA and SDLAs provided concerning costs not accounted for in the NPRM; we considered these comments when revising the cost estimates for the final rule. The Agency notes that State-based due process requirements, such as notice, already exist, and are therefore not imposed by this final rule. For example, the rule does not require that States notify drivers of an impending downgrade. Therefore, to the extent a State incurs notification costs, they derive directly from State-based requirements. (As discussed above, FMCSA intends to notify drivers of the downgrade requirement when informing them that

a drug or alcohol violation has been reported to the Clearinghouse.) FMCSA agrees that States will likely need to train their employees on any new process and procedures related to the final rule. FMCSA assumes this will occur as part of routine training related to periodic changes in statutory or regulatory requirements, and therefore does not estimate a separate training cost in this rule. FMCSA agrees that States will incur costs for customer service inquiries and for initial IT development, and ongoing operations and maintenance, in order to comply with this rule. In Section XI., the Agency explains the assumptions used to determine cost impacts of the final rule on SDLAs. FMCSA acknowledges that AAMVA may need to make updates to CDLIS in order to transmit additional data elements on the driver record and incorporated a cost for CDLIS updates in Section XI.

Comments Outside the Scope of the NPRM

An individual commenter suggested increased oversight on the substance abuse professionals who administer RTD requirements. Another individual, noting that motor carrier employers must pay a fee to access Clearinghouse information, recommended that FMCSA also charge the States a fee for their use of the Clearinghouse. One commenter thought the current regulations are too harsh and suggested that drivers who fail a drug test for the first time should have the violation removed from their record if no further program violations occur within one year. The NSTA, noting increased delays in CLP and CDL issuance due to COVID-related backlogs, suggested that FMCSA consider the merits of a "School Bus Only" CDL as a means of ensuring qualified drivers. The Trucking Alliance proposed that FMCSA amend the definition of *actual knowledge* in 49 CFR 382.107, to include the employer's knowledge of a driver's positive hair test result. Several entities, including the Alliance, TCA, and the ATA, supported some form of employer notification of a driver's prohibited status, or a change in the driver's licensing status. The ATA and TCA proposed that FMCSA expand the 30-day "lookback" provision, currently applicable only to pre-employment queries, to annual queries as well.

FMCSA Response: With the exception of minor conforming changes, the NPRM did not propose changes to FMCSA's drug and alcohol program, or to the operation of the Clearinghouse vis-à-vis employers. The comments summarized above are, therefore, outside the scope of the proposed rule,

²⁴ As noted in the NPRM, the current compliance date of January 6, 2023, which applies to the States' query requirements set forth in 49 CFR 382.725(a) and 383.73, will be replaced by the date established by the final rule.

and FMCSA does not respond to these suggestions in this final rule.

VII. International Impacts

FMCSA's drug and alcohol program requirements apply to drivers who are licensed in Canada and Mexico and operate CMVs in commerce in the United States, and to their employers (49 CFR 382.103(a)). Accordingly, foreign-licensed drivers and their employers are subject to the CMV driving prohibitions set forth in 49 CFR 382.501(a) and (b). Canadian and Mexican licensing authorities are not authorized users of the Clearinghouse, however, as MAP-21 granted direct access only to the SDLAs in the 50 States and the District of Columbia.

In the NPRM, FMCSA described how it would enforce the CMV driving prohibition for drivers licensed in Canada and Mexico. Currently, a foreign-licensed driver's operating status is available to enforcement officials. Enforcement personnel who electronically initiate a foreign-licensed driver status request through *cdlis.dot.gov* or Query Central can discern that, under § 382.501(a), the driver is prohibited from operating a CMV in the United States. The foreign-licensed driver is cited for violating the driving prohibition and placed out of service at roadside.

FMCSA also notifies the foreign-licensed driver that he/she is prohibited from operating a CMV within the borders of the United States until he or she complies with RTD requirements, as required by § 382.503. When the driver's negative RTD test is reported to the Clearinghouse, FMCSA removes the prohibited status designation from the Clearinghouse and notifies the driver that the individual is no longer prohibited from operating a CMV in the United States. In addition, FMCSA notifies drivers if they are erroneously identified as prohibited from operating a CMV and removes the prohibited status from the Clearinghouse. The Agency notes that, because these procedures rely on FMCSA's existing enforcement authority, no revision to 49 CFR parts 382, 383, or 384 is necessary.

VIII. Privacy Act Applicability

MAP-21 requires that the "release of information" from the Clearinghouse comply with the applicable provisions of the Privacy Act of 1974 (49 U.S.C. 31306a(d)(1)). The Privacy Act (5 U.S.C. 552a) prohibits the disclosure of information maintained in a Federal system of records, except to the extent disclosures are specifically permitted by the Privacy Act, or pursuant to a written request by, or with the prior written

consent of, the individual to whom the record pertains.²⁵ Section (b)(3) of the Privacy Act permits disclosure of information from a system of records when the disclosure is a "routine use." As defined in 5 U.S.C. 552a(a)(7), "the term 'routine use' means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected." Under the Privacy Act, each routine use for a record maintained in the system, including the categories of users and the purpose of such use, must be included in a System of Records Notice (SORN) published in the **Federal Register**.

The Agency published a SORN for the new system of records titled "Drug and Alcohol Clearinghouse (Clearinghouse)," on October 22, 2019 (84 FR 56521). The SORN describes the information to be maintained in the Clearinghouse and the circumstances under which the driver's consent must be obtained prior to the release of information to a current or prospective employer. The SORN also identifies the general and specific routine uses applicable to the Clearinghouse, including the disclosure of a driver's CMV operating status (prohibited or not prohibited) to an SDLA. As explained in the SORN, this routine use permits the SDLA to verify the driver's eligibility to obtain or hold a CLP or CDL, as required by MAP-21.

IX. Explanation of Changes From the NPRM

49 CFR Part 382

Currently 49 CFR 382.725(a)(1) permits SDLAs to access DACH information for CDL applicants on a voluntary basis until January 6, 2023; subparagraph (a)(2) requires the SDLA to check the DACH prior to issuing a CDL on or after January 6, 2023. In the NPRM, FMCSA proposed to revise 49 CFR 382.725 by combining subparagraphs (a)(1) and (2), which would account for the fact that, as of the compliance date of this final rule, subparagraph (a)(1), granting SDLAs' permissive access to the DACH, would be moot. However, FMCSA's proposed revision inadvertently eliminated the permissive Clearinghouse access provision for SDLAs, which the Agency adopted in the 2019 final rule extending the compliance date for the SDLA's mandatory query requirements in 49 CFR 382.725 and 383.73.²⁶ FMCSA

²⁵ See 5 U.S.C. 552a(b). The Clearinghouse final rule requires the individual's prior written consent for the release of certain Clearinghouse records to employers. See 49 CFR 382.703.

²⁶ 84 FR 68052 (Dec.13, 2019).

added subparagraph (1) to 49 CFR 382.725(a) in 2019 so that States wishing to voluntarily access the DACH could do so until the compliance date established by this final rule. Consistent with that intent, the Agency retains 49 CFR 382.725(a)(1) and changes the compliance date to November 18, 2024. FMCSA also revises subparagraph (a)(1) to clarify that SDLAs may check the DACH record of CLP applicants. As proposed, FMCSA updates the compliance date for the mandatory query and requires that CLP holders be included within the scope of the mandatory query in subparagraph(a)(2). The Agency adopts the proposed revisions to 49 CFR 382.503 and 382.717 without change.

49 CFR Parts 390 and 392

FMCSA also adopts a 3-year compliance date for the requirements set forth in 49 CFR 390.3, 390.3T and 392.15. The Agency makes this change to comply with 49 CFR 350.303(b), which requires that, no later than 3 years after the effective date of any new amendment to the FMCSRs, the State must amend its laws, regulations, standards, and orders to ensure compatibility.

49 CFR 383.73(a)(3), (b)(10), (c)(10), (d)(9), (e)(8), and (f)(4)

FMCSA adopts the non-issuance requirements in 49 CFR 383.73 as proposed, but for one minor change: in § 383.73(d)(9), the H endorsement is added to the scope of the provision, to clarify that, if a driver seeking to renew the H endorsement is prohibited from operating a CMV, the SDLA must not renew the endorsement.

49 CFR 383.73(q)

As noted above, the Agency adopts the mandatory downgrade requirement, proposed as one of two regulatory alternatives, in this final rule. FMCSA made two changes in the downgrade procedures set forth in 49 CFR 383.73(q). First, the time period in which SDLAs must complete and record the downgrade on the CDLIS driver record is extended from 30 days, as proposed, to 60 days from the date the SDLA receives notification from FMCSA of the driver's prohibited status. The Agency makes this change in response to comments that 30 days did not provide adequate time for some SDLAs to comply with driver notice and other State-based due process requirements. The final rule does not prohibit SDLAs from completing the downgrade in less than 60 days, if their State processes permit them to do so. Second, the Agency adds a requirement, set forth in

§ 383.73(q), new subparagraph (3), “Reinstatement after Clearinghouse error correction,” that SDLAs must promptly reinstate the commercial driving privilege following notification that FMCSA incorrectly identified the driver as prohibited from operating a CMV. Further, any reference to the driver’s prohibited status must be expunged from his or her State-maintained driving record. SDLAs will rely on their existing error correction processes to comply with these requirements.

49 CFR 383.5

The term *CDL downgrade* is currently defined, in 49 CFR 383.5, subparagraph (4) to reference a situation in which “a State removes the CDL privilege from the driver’s license.” FMCSA proposed to amend the definition of *CDL downgrade* in subparagraph (4) by specifying that the privilege is removed by changing the commercial status from “licensed” to “eligible” on the CDLIS driver record. FMCSA also proposed to add a similar definition of *CLP downgrade* to subparagraph (4). The Agency proposed the revisions to clarify how SDLAs would accomplish the downgrade. In the final rule, FMCSA does not amend subparagraph (4) as proposed. Instead, the final rule amends subparagraph (4) only to clarify that the term *CDL downgrade* also includes the removal of the CLP privilege. The reason for this change from the proposal is that some commenters understood the proposed revisions to mean that States could remove the CLP or CDL only by changing the commercial status in the manner proposed. As explained above, that was not FMCSA’s intention. At their discretion, SDLAs may also disqualify the CLP or CDL, in accordance with State law.

X. Section-by-Section Analysis

FMCSA amends 49 CFR parts 382, 383, 384, 390, and 392 as follows.

A. Part 382

Part 382 establishes controlled substances and alcohol use and testing requirements for CLP and CDL holders and their employers. FMCSA amends part 382 in the following ways.

Section 382.503

This section currently states that drivers who violate drug or alcohol use or testing prohibitions cannot resume safety-sensitive functions, including driving a CMV, until completing RTD requirements. FMCSA designates the current provision as paragraph (a). New paragraph (b) clarifies that drivers whose license was downgraded due to

a drug and alcohol program violation cannot resume driving a CMV until the State reinstates the CLP or CDL privilege.

Section 382.717

Under the current § 382.717(a)(2)(i), drivers may request that FMCSA remove from the Clearinghouse an employer’s report of actual knowledge, based on the issuance of a citation for driving under the influence (DUI) in a CMV, if the citation did not result in the driver’s conviction. FMCSA revises subparagraph (a)(2)(i) by deleting the reference to removal of the employer’s actual knowledge report from the Clearinghouse and providing, instead, that the driver may request that FMCSA add documentary evidence of non-conviction of the offense of DUI in a CMV to the driver’s Clearinghouse record.

Section 382.725

Subparagraphs (a)(1) and (a)(2) of Section 382.725 currently state that, prior to January 6, 2023, SDLAs may determine whether a CDL applicant is qualified to operate a CMV by accessing the Clearinghouse as an authorized user, and that, beginning January 6, 2023, SDLAs must request information from the Clearinghouse for CDL applicants. Section 382.725(b) currently provides that a driver applying for a CDL is deemed to have consented to the release of information from the Clearinghouse. FMCSA amends § 382.725(a)(1) and (2) by changing the date from January 6, 2023, to November 18, 2024. FMCSA also revises paragraphs (a) and (b) to clarify that the provisions also apply to CLP applicants.

B. Part 383

Part 383 sets forth the requirements for the issuance and administration of CLPs and CDLs. FMCSA amends part 383 in the following ways.

Section 383.5

Subparagraph (4) of the definition of *CDL downgrade* currently provides that the term means that a State removes the CDL privilege from the driver’s license. FMCSA revises subparagraph (4) to clarify that the term also includes the removal of the CLP privilege.

Section 383.73

FMCSA adds subparagraph (3) to paragraph (a) and revises paragraphs (b)(10); (c)(10); (d)(9); (e)(8); and (f)(4) to require that if, in response to the required request for information, FMCSA notifies the SDLA that, pursuant to § 382.501(a), the individual is prohibited from operating a CMV, the

SDLA must not complete the specified CLP, CDL, non-domiciled CDL, or non-domiciled CLP transaction, and must initiate the downgrade process, as set forth in new paragraph (q). In addition, FMCSA makes a non-substantive conforming change to paragraphs (b)(10); (c)(10); (d)(9); (e)(8); and (f)(4) by deleting the phrase “in accordance with § 382.725 of this chapter”, which is unnecessary. FMCSA also revises paragraph (d)(9) to clarify that the SDLA must not renew an H endorsement if FMCSA notifies the SDLA that the individual is prohibited from operating a CMV, and must initiate a downgrade, as applicable. FMCSA revises paragraph (f)(4) to clarify that the requirement also applies to non-domiciled CLPs.

FMCSA adds new paragraph (q) to specify the actions that SDLAs are required to take upon receipt of information from FMCSA. SDLAs must complete and record a CLP or CDL downgrade on the CDLIS driver record within 60 days of receiving notification from FMCSA that the driver is prohibited from operating a CMV due to a drug and alcohol program violation. SDLAs will rely on established State processes to initiate and complete the downgrade. Under subparagraph (1), headed “Termination of the downgrade process when the driver is no longer prohibited”, if FMCSA notifies the SDLA that the driver completed the RTD process before the SDLA completes and records the downgrade on the CDLIS driver record, the SDLA, if permitted by State law, must terminate the downgrade process at that point. Subparagraph (2), headed “Reinstatement after FMCSA notification that the driver is no longer prohibited”, provides that drivers who complete RTD after the downgrade is completed and recorded by the SDLA will be eligible for reinstatement of the CLP or CDL privilege to their driver’s license. Subparagraph (3), headed “Reinstatement after Clearinghouse error correction”, requires SDLAs to reinstate the CDL or CLP privilege to a driver’s license as expeditiously as possible, following notification by FMCSA that the driver’s prohibited status, previously reported to the SDLA, was based on erroneous Clearinghouse information. States must also clear the individual’s driving record of any reference to the driver’s prohibited status.

C. Part 384

The purpose of Part 384 is to ensure that the States comply with 49 U.S.C. 31311(a). FMCSA amends part 384 in the following ways.

Section 384.225

FMCSA revises this section by adding new subparagraph (a)(3) to require the State to post and maintain, as part of the CDLIS driver record, the removal of the CLP or CDL privilege from the driver's license, in accordance with § 383.73(q).

Section 384.235

FMCSA amends this section by establishing the date by which the State must begin complying with the requirements set forth in § 383.73 applicable to request for Clearinghouse information, noncompletion of the transaction, downgrade, and reinstatement.

Section 384.301

This section sets forth the general requirements for the State to be in substantial compliance with 49 U.S.C. 31311(a). FMCSA adds new paragraph (o) to require that the State be in substantial compliance with the requirements in §§ 383.73, 384.225, and 384.235 no later than the compliance date established by this final rule.

D. Part 390

This part, entitled “Federal Motor Carrier Safety Regulations; General”, establishes general applicability provisions, definitions, general requirements, and information as they pertain to persons subject to 49 CFR chapter 3. FMCSA amends § 390.3T(f)(1) to add new § 392.15 to the list of provisions that remain applicable to school bus operations as defined in § 390.5T. FMCSA also amends § 390.3(f)(1) in the same way, so when the temporary section is removed and the changes made by the Unified Registration System final rule take effect,²⁷ the change made by this final rule will also be in effect.

E. Part 392

This part, entitled “Driving of Commercial Motor Vehicles”, sets forth requirements pertaining to the management, maintenance, operation or driving of CMVs. FMCSA adds new § 392.15 to prohibit any driver subject to § 382.501(a) from operating a CMV.

XI. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA has considered the impacts of this rule under E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory

Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and DOT's regulatory policies and procedures. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) has determined that this rulemaking is not a significant regulatory action under section 3(f) of E.O. 12866. Accordingly, OMB has not reviewed it under that E.O.

As described above, this rule prohibits SDLAs from issuing, renewing, upgrading, or transferring the CDL, or issuing, renewing, or upgrading the CLP, of any driver who is prohibited from operating a CMV due to drug and alcohol program violations. In addition, SDLAs will be required to downgrade the CLP or CDL of drivers who are prohibited from operating a CMV due to drug and alcohol program violations. FMCSA believes that the rule will increase safety by enhancing the enforcement of the current CMV driving prohibition. These factors are discussed below.

Need for Regulation

The 2016 Clearinghouse final rule included the MAP-21 requirement that SDLAs check the Clearinghouse prior to renewing or issuing a CDL. However, the rule did not address how SDLAs should use Clearinghouse information for drivers licensed, or seeking to become licensed, in their State. Therefore, under the current rule, drivers who violate the drug and alcohol program can continue to hold a valid CLP or CDL, even though they are prohibited from operating a CMV until completing RTD. These drivers, who are illegally operating a CMV, are thus able to evade detection by enforcement personnel. The Agency considers this result a form of market failure caused by “inadequate or asymmetric information,” as described in OMB Circular A-4.²⁸ The final rule addresses this failure by improving the flow of information to SDLAs and enforcement officials from the Clearinghouse.

Cost Impacts

The RIA published with the Clearinghouse final rule in 2016 (2016 RIA) assumed that SDLAs would incur no costs to query the Clearinghouse using CDLIS. However, the 2016 RIA did not include SDLAs' IT development costs or operating and maintenance expenses (O&M) associated with the

interface that would connect the Clearinghouse and CDLIS. Hence, they are accounted for in the estimate of the costs associated with this rule.

The NPRM proposed two alternatives related to the States' use of Clearinghouse information, and two methods for electronically transmitting information from the Clearinghouse to the SDLAs. The estimated cost of the proposed rule varied based on the regulatory alternative and method of information transmission. The final rule follows the Agency's preferred alternative by requiring a license downgrade, but allows the SDLA to choose the most cost beneficial method of information transmission. This rule will result in IT costs for SDLAs, AAMVA, and the Federal government, and in opportunity costs for drivers and motor carriers.

In the NPRM, FMCSA proposed two methods for information transmission: CDLIS and a web-based services option. The Agency estimated that the CDLIS option would be more costly. Some States commented they preferred to use CDLIS due to familiarity with that platform, while others were not sure which method would be most cost effective. Under the final rule, SDLAs can choose between transmitting information via CDLIS or a web-based services platform.

As provided by MAP-21 and current FMCSA regulations, SDLAs, prior to issuing a CLP or CDL, will be required to check the CDLIS driver record to ensure that the driver has not been disqualified in another State and that other regulatory requirements have been met. This final rule, by electronically linking the CDLIS pointer system either directly to the Clearinghouse or indirectly through a web-based services call, will allow this record check to electronically capture relevant Clearinghouse information (*i.e.*, a driver's prohibited status) along with other driver-specific data, such as moving violations or medical certification status. Thus, the Agency intends that SDLAs will therefore request information from the Clearinghouse by initiating a check of the CDLIS driver record. Under either method of transmission, no additional query or request by the SDLA will be required at the time of the licensing transaction, thereby minimizing the burden of performing the required check of the Clearinghouse.

Because SDLAs already perform CDLIS driver record checks when conducting a commercial license transaction, FMCSA finds that SDLAs would not incur labor costs to “pull” Clearinghouse information through

²⁸ OMB, Circular A-4: Regulatory Analysis, September 17, 2003, pp. 4-5. Available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>, (accessed April 22, 2021).

²⁷ 82 FR 5292 (Jan. 17, 2017).

CDLIS by performing a query. The Agency also assumes that AAMVA would not charge SDLAs additional CDLIS-related costs to receive driver-specific violation information “pushed” to the SDLAs by FMCSA, because CDLIS already provides daily updates of licensing information to the SDLAs. FMCSA intends that Clearinghouse information would be an additional data element included in the daily transmission. Thus, the Agency finds that SDLAs will not incur transaction-specific CDLIS costs as a result of this rule.

Using the existing CDLIS platform will result in costs to SDLAs for initial system development, and to make the needed upgrades and modifications, as well as ongoing operations and maintenance expenses. In the NPRM, the Agency reviewed four SDLA grant applications submitted in 2017 for IT system upgrades needed to interface and receive information from the NRCME database, and used the grant applications as a proxy for the IT development costs SDLAs would incur using CDLIS to access Clearinghouse information. FMCSA estimated that each SDLA’s IT development costs would total approximately \$200,000. In preparation for the final rule, FMCSA reviewed 2020 Commercial Driver’s License Program Implementation (CDLPI) grant applications and found that four States requested funds focused on the Clearinghouse, with an average cost of \$300,000. However, some of these applications deal with Clearinghouse issues unrelated to this final rule, and thus FMCSA assumes that \$300,000 per SDLA would be an overestimate for costs attributed to using the CDLIS platform.

SDLAs will also have the option of transmitting information from the Clearinghouse to the SDLAs using a web-based services call, which relies on cloud-based technology. The capacity for this alternative would reside within the DOT’s Amazon Web Service (AWS) cloud. By using the DOT AWS cloud, FMCSA would be able to make efficient updates to the system on an as-needed basis. As explained below, FMCSA anticipates that the web-based services call IT development cost will average approximately \$56,500 per SDLA.

AAMVA indicated it may incur costs for aligning the Clearinghouse information with disqualification data that already exists in CDLIS. FMCSA will work with AAMVA to determine the necessity and extent of these costs, but for analysis purposes estimates that they would not be greater than \$200,000 for development, with an annual operations and maintenance cost of

\$40,000. FMCSA will incur costs of approximately \$1 million for development of a web-based services application and approximately \$200,000 for annual operations and maintenance costs in years 2 through 10 of the analysis.

In order to implement a web-based services call, FMCSA will develop an interface between the Clearinghouse and the SDLAs. FMCSA envisions that the interface would connect seamlessly to the existing State interface so that when a State employee initiates the CDLIS driver record check, the State system would simultaneously query the Clearinghouse. FMCSA would provide the application programming interface (API) code, or other technical specifications, and work with the States to integrate the interface into their existing technology platforms. In developing this interface, FMCSA would leverage the current FMCSA web-based services calls, such as Query Central, to reduce development costs wherever possible.

SDLAs using this method will incur costs for initial modification of their systems to interface with the Clearinghouse, and annual operations and maintenance expenses. FMCSA expects that SDLAs’ costs to implement the interface specifications would vary based on the characteristics of their individual IT systems. The Agency’s IT staff estimated a representative initial/upfront cost taking into account that some States currently use a mainframe application and others use an existing web interface. The initial development costs for each method to interface with the Clearinghouse were estimated based on the labor hours it would take a programmer to develop an application for use in a mainframe environment and in a non-mainframe environment. Developing a web interface in a mainframe environment is estimated to take 1,080 hours. Developing a web interface in a non-mainframe environment is estimated to take 360 hours. These hours were monetized in 2019 dollars using the United States Department of Labor, Bureau of Labor Statistics (BLS) \$41.61 per hour median wage for a computer programmer.²⁹ The hourly wage is adjusted for a 73 percent fringe benefit rate obtained from the BLS June 2019 “Employer Cost of Employee Compensation News Release,”³⁰ and a 15.9 percent overhead

rate based on indirect cost rates provided by States in their 2020 CDLPI grant applications. The resulting labor cost is \$78.53 per hour. At that hourly rate, the cost for a programmer to develop an interface in a non-mainframe environment is estimated at \$28,271 (360 hours × \$78.53 per hour) and \$84,812 (1,080 hours × \$78.53 per hour) in a mainframe environment. The average of these two cost estimates results in an initial IT development of \$56,500 per SDLA (rounded to the nearest hundred).

Because the Agency is allowing SDLAs to choose the method that works best for their particular system and framework, FMCSA continues to estimate initial IT development costs for SDLAs to be \$200,000 per SDLA, accounting for both CDLIS costs of likely just below \$300,000 and web-based services costs of less than \$60,000. Multiplying this cost by the number of SDLAs (51) results in a total of \$10.2 million (\$200,000 × 51) in SDLA initial/upfront development costs. This one-time cost occurs in the first year of the 10-year analysis period.

The Agency assumes that SDLAs’ annual operations and maintenance expenses would be equal to 20 percent of the upfront costs, or \$40,000 (\$200,000 × 20 percent). Multiplying the operations and maintenance expense rate by the number of SDLAs resulted in \$2.04 million of annual operations and maintenance expenses (\$40,000 × 51 SDLAs). The Agency assumes that SDLAs would incur operations and maintenance expenses annually, beginning in the second year of the 10-year analysis period. Operations and maintenance expenses over the 10-year analysis period are estimated at \$18.4 million (\$2.04 million × 9 years). FMCSA estimates that the total undiscounted IT development and operations and maintenance expenses over the 10-year analysis period are \$28.6 million (\$10.2 million IT development costs + \$18.4 million operations and maintenance expenses).

In response to comments from two States, FMCSA includes a recurring cost to manage in-person and phone or email inquiries related to the downgrade procedures. The States did not indicate how long it takes to handle customer service inquiries, but FMCSA estimates that an average of one hour per downgraded license is a conservative

²⁹ This hourly median wage is for the BLS–SOC 15–1251 computer programmer. See <https://www.bls.gov/oes/current/oes151251.htm> (accessed November 2, 2020).

³⁰ BLS, “Employer Cost of Employee Compensation 4th Quarter News Release,” Table 4—employer Costs for Employee Compensation for

private industry workers by occupational and industry group, available at https://www.bls.gov/news.release/archives/ecec_03192020.pdf (accessed Nov. 2, 2020). The fringe benefit rate is the ratio of hourly wage for average hourly wage for a private industry worker and the associated hourly benefit rate (73 percent = \$25.85/14).

estimate, and values this time at a loaded median hourly rate of \$31.50 for customer service representatives.³¹ This results in an annual cost of approximately \$159,000 (5,045 downgraded licenses per year × 1 hour × \$31.50).

In sum, FMCSA estimates 10-year total costs for SDLAs to be approximately \$30.1 million undiscounted. At a 7 percent discount rate, the 10-year total cost is estimated at \$23.1 million and the annualized cost is estimated at \$3.3 million. FMCSA notes that States can apply for CDLPI grant program funding to offset the cost associated with IT development and operations and maintenance.

FMCSA will incur initial IT development costs of just over \$1.0 million in 2019 dollars in the first year of the 10-year analysis period. FMCSA would incur annual operations and maintenance expenses of \$203,000 (\$1.02 million × 20 percent) beginning in the second year of the 10-year analysis period. Over the remaining 9 years of the analysis period, the Agency will incur \$1.8 million of operations and maintenance expenses (\$203,000 × 9 years). The sum of initial IT development costs and annual O&M expenses results in FMCSA incurring total undiscounted costs of \$2.8 million over the 10-year analysis period (\$1.0 million + \$1.8 million). At a 7 percent discount rate, the Agency is estimated to incur \$2.2 million in IT development and operations and maintenance expenses over the 10-year analysis period. The annualized cost at a 7 percent discount rate is estimated at \$0.3 million.

Driver Opportunity Cost and CLP/CDL Reinstatement Cost

Under the final rule, a driver could incur an opportunity cost equal to the income forgone between the time he or she is eligible to resume operating a CMV (*i.e.*, when an employer reports a negative RTD test result to the Clearinghouse) and when the SDLA reinstates the commercial privilege to the driver's license.

The estimate of opportunity costs drivers may incur is a function largely of the number of drivers that SAPs refer to outpatient education programs versus intensive outpatient treatment (IOT) programs. In the 2016 RIA, the Agency assumed an education program would be completed in 16 hours and an IOT

program would be completed in 108 hours over 12 weeks. The final rule requires SDLAs to record a downgrade on the driver's CDLIS record within 60 days. If the driver completes the RTD process before the SDLA records a downgrade in CDLIS, the SDLA would be required to terminate the downgrade, consistent with State law. A driver referred to a 16-hour education program by a SAP may complete the RTD process before the SDLA records the downgrade in CDLIS. In this case, a driver would be qualified to operate a CMV without having to comply with State-established procedures to reinstate the CMV driving privilege and would not incur opportunity costs.

In the 2016 RIA, the Agency assumed that 75 percent of drivers who violated the drug and alcohol program would be referred to a 16-hour education program. The remaining drivers would be referred to a 108-hour IOT program. In July 2018, the Substance Abuse and Mental Health Service Administration (SAMHSA), published a report titled *National Survey of Substance Abuse Treatment Services (N-SSATS): 2017. Data on Substance Abuse Treatment Facilities*. SAMHSA reported that 82 percent of individuals in outpatient programs participated in education programs. The remaining 18 percent participated in IOT programs.³² FMCSA reviewed the 2018 SAMHSA survey report and found that the client characteristics regarding outpatient program attendance were not reported, and therefore the 2017 report provides the most recent estimate of the percentage of individuals completing education programs. The Clearinghouse, which has been operational since January 2020, accurately reports driver count information that informs the percentage of drivers who complete RTD procedures within the 60-day timeframe.³³ However, this data was collected during the coronavirus disease 2019 (COVID-19) pandemic, which has had significant short-term impacts on the U.S. economy and labor market. While the long-term impacts remain unclear, FMCSA does not think it prudent to estimate costs over a 10-year

period based on information collected during the COVID-19 pandemic, which drastically affected employment, freight rates, and even mental health and substance abuse prevalence. Further, FMCSA did not receive comments regarding any inaccuracy of the SAMHSA data and therefore continues to rely on it for the purposes of this analysis.

Based on the U.S. DOT's survey data for 2018, extrapolated to the entire CDL population, FMCSA estimates that 62,279 drivers will test positive and be required to complete the RTD process annually.³⁴ The 2016 RIA estimated that 45 percent, or 28,026 of these drivers, will complete the RTD process.³⁵ Based on SAMHSA's survey, the Agency estimates that 82 percent, or 22,981 of the 28,026 drivers, will complete the RTD process before SDLAs record the downgrade and will not incur opportunity costs.³⁶ The remaining 5,045 drivers (28,026 drivers × 18 percent) presumably will be referred to an IOT program and be required to comply with any reinstatement procedures established by the State that could cause a driver to incur opportunity costs.

Depending on the State, a driver may be required to appear in person at the SDLA to complete the reinstatement process that could require the driver to incur opportunity costs for the time to travel to and from the SDLA. Some SDLAs allow the transaction to be completed by email or through the SDLA website. For purposes of this analysis, the Agency assumes that drivers will need to complete the transaction in person, which may result in an overestimation of the cost to drivers. The Agency assumes that it will take one day for a driver to travel to an SDLA and complete the reinstatement

³⁴ U.S. DOT Agency MIS data. Available at: https://www.transportation.gov/odapc/DOT_Agency_MIS_Data. Accessed on November 2, 2020.

³⁵ DOT FMCSA Commercial Driver's License Drug and Alcohol Clearinghouse: Final Rulemaking Regulatory Impact Analysis. December 13, 2016. Available at: <https://beta.regulations.gov/document/FMCSA-2011-0031-0183>.

³⁶ FMCSA notes that, while States have 60 days to complete a downgrade of the CLP/CDL, they may elect to record the downgrade sooner, thereby reducing the time frame for drivers to complete the RTD process requirements prior to the downgrade. If this occurs, drivers referred to the 16-hour education program may be subject to reinstatement procedures at the SDLA. FMCSA is unable to estimate the likelihood or frequency of such an occurrence, and continues to assume all drivers referred to a 16-hour education program will complete the RTD process prior to the State recording the downgrade. The Agency believes this is a reasonable assumption, particularly given the increased incentive to quickly complete the RTD process following the notification to drivers of an impending downgrade.

³² The report is available at <https://www.samhsa.gov/data/report/national-survey-substance-abuse-treatment-services-n-ssats-2017-data-substance-abuse>, Table 5-1a (accessed June 16, 2019).

³³ As of January 1, 2021, the Clearinghouse recorded just over 52,000 drivers with a drug or alcohol violation, of which more than 60% had not started the RTD process. Over 30% of drivers with a violation had either started or completed RTD. While this data is logically consistent with the assumptions in this analysis, FMCSA cannot determine how the COVID pandemic affected either the total number of violations or the RTD process and is not using Clearinghouse data to inform impact estimates at this time.

³¹ The hourly median wage for the BLS-SOC 43-4051 Customer Service Representative is \$16.69. FMCSA adjusts this wage rate using the previously identified fringe benefits rate of 73 percent and the overhead rate of 15.9 percent. See <https://www.bls.gov/oes/current/oes151251.htm>.

process. Thus, drivers will incur opportunity cost for time spent traveling and out-of-pocket travel costs. The Agency's estimate of driver opportunity costs and reinstatement costs is based on the following assumptions:

1. One day to travel to and from the SDLA and complete the reinstatement process.
2. 10 hours of lost wages.
3. 5,045 drivers subject to mandatory downgrades.
4. A representative driver wage of \$31.00 per hour to estimate income forgone.
5. \$0.575 per-mile cost for use of private vehicle.³⁷
6. 50 miles round-trip to the SDLA.

Based on these assumptions, the upper bound of annual opportunity costs for one day spent traveling to the SDLA and completing the reinstatement process is estimated at \$1.6 million ((10 hours × 5,045 drivers × \$31 per hour) + (5,045 drivers × 50 miles × \$0.575 per mile)), and the 10-year total cost is estimated at \$16.3 million. At a 7 percent discount rate, the 10-year cost is estimated at \$11.5 million and the annualized cost is estimated at \$1.6 million.

Drivers may also incur reinstatement costs attributed to SDLA requirements for restoring the commercial privilege, such as payment of a reinstatement fee, and partial or full retesting.³⁸ The States have established a broad spectrum of procedures for reinstatement of the CLP/CDL privilege to the driver's license following a downgrade due to invalid medical certification as required by § 383.73(o)(4), and the Agency expects that the States will adopt or modify existing procedures when downgrading a CLP/CDL due to a drug or alcohol violation. FMCSA reviewed current procedures used by the States for drivers whose CLP or CDL has been downgraded for failure to maintain their medical certification. The Agency is aware that about half of the States require knowledge and/or skills retesting before removing a downgrade. However, in these States, retesting is required only if a driver is not able to present a new medical certificate before the expiration of a prescribed grace period. None of these States has a retesting grace period less than six

³⁷ The mileage rate is the General Services Administration current reimbursement rate for use of private vehicles. The mileage rate for private vehicle use is available at <https://www.gsa.gov/travel/plan-book/transportation-airfare-rates-pov-rates/private-owned-vehicle-pov-mileage-reimbursement-rates> (accessed Oct. 29, 2020).

³⁸ A requirement to retake the knowledge and skills test would cause the driver to forgo income during the 14-day waiting period required before taking the skills test.

months. In the 2016 RIA, the Agency conservatively assumed that it would take a driver 12 weeks to complete a 108-hour program based on one 9-hour session per week. Thus, the Agency finds that drivers referred to IOT programs will complete the IOT program and the RTD process without having to retest to have the CLP or CDL privilege restored to their license. Therefore, FMCSA is not estimating reinstatement costs or fee payments resulting from this rule.

Motor Carrier Opportunity Costs

Motor carrier opportunity costs are estimated because drivers subject to reinstatement would not be eligible to resume safety-sensitive functions, such as driving, until the SDLA restores the CLP or CDL privilege to the driver's license. This represents a change from current requirements in parts 382 and 40, which permit resumption of safety-sensitive functions immediately following a negative RTD test result. Thus, motor carriers may also incur opportunity costs based on the profits forgone from the loss of productive driving hours between the time the driver completes the RTD process and State reinstatement. The Agency estimates that a motor carrier will lose 10 hours of productive driving time while a driver completes the reinstatement process. FMCSA bases this estimate on current processes the States employ to reinstate a CLP or CDL privilege following a downgrade of the driver's license due to invalid medical certification.

In concert with the driver opportunity cost estimates, the Agency estimates that motor carriers would lose 50,446 hours of productive driving time each year (5,045 drivers × 10 hours) while drivers complete the reinstatement process. Broadly speaking, the opportunity cost to the motor carrier (the firm) of a given regulatory action is the value of the best alternative that the firm must forgo in order to comply with the regulatory action. In this analysis, FMCSA follows the methodology used in the Entry-Level Driver Training rulemakings published in 2016³⁹ and 2019⁴⁰ and values the change in time spent in nonproductive activity as the opportunity cost to the firm, which is represented by the now attainable profit, using three variables: The marginal cost of operating a CMV, an estimate of a typical average motor carrier profit margin, and the change in nonproductive time.

³⁹ 81 FR 88732 (Dec. 8, 2016).

⁴⁰ 84 FR 10437 (Mar. 21, 2019).

The American Transportation Research Institute (ATRI) report, *An Analysis of the Operational Costs of Trucking: 2019 Update*, found that marginal operating costs were \$71.78 per hour in 2018.⁴¹ These marginal costs include vehicle-based costs (e.g., fuel costs, insurance premiums, etc.), and driver based costs (i.e., wages and benefits).

Next, the Agency estimated the profit margin for motor carriers. Profit is a function of revenue and operating expenses, and ATA defines the operating ratio of a motor carrier as a measure of profitability based on operating expenses as a percentage of gross revenues.⁴² Armstrong & Associates, Inc. (2009) states that trucking companies that cannot maintain a minimum operating ratio of 95 percent (calculated as Operating Costs ÷ Net Revenue) will not have sufficient profitability to continue operations in the long run.⁴³ Therefore, Armstrong & Associates states that trucking companies need a minimum profit margin of 5 percent of revenue to continue operating in the future. Transport Topics publishes data on the "Top 100" for-hire carriers, ranked by revenue.⁴⁴ For 2014, 39 of these Top 100 carriers also had net income information reported by Transport Topics. FMCSA estimates that the 39 carriers with both revenue and net income information have an average profit margin of approximately 4.3 percent for 2014. For 2018, 33 of these Top 100 carriers had net income information reported by Transport Topics, with an average profit margin of approximately 6 percent for 2018.⁴⁵ The higher profit margin experienced in 2018 is reinforced by a Forbes article that found net profit margin for freight trucking companies "expanded to 6 percent in 2018, compared with an annual average of between 2.5 percent and 4 percent each

⁴¹ ATRI. *An Analysis of the Operational Costs of Trucking: 2019 Update*. October 2019. Table 10, pg. 19. Available at: <https://truckingresearch.org/wp-content/uploads/2019/11/ATRI-Operational-Costs-of-Trucking-2019-1.pdf> (accessed April 19, 2021). Source data are assumed to be presented in 2018 dollar terms.

⁴² ATA. *American Trucking Trends 2015*. Page 79.

⁴³ Armstrong & Associates, Inc. *Carrier Procurement Insights*. 2009. Pages 4–5. Available at: <https://www.3plogistics.com/product/carrier-procurement-insights-trucking-company-volume-cost-and-pricing-tradeoffs-2009/> (accessed Jan. 5, 2016).

⁴⁴ Transport Topics. 2014. *Top 100 For-Hire Carriers*. Available at: <http://ttnews.com/top100/for-hire/2014> (accessed April 19, 2021).

⁴⁵ Transport Topics. 2018. *Top 100 For-Hire Carriers*. Available at: <https://www.ttnews.com/top100/for-hire/2018> (accessed April 19, 2021).

year since 2012.”⁴⁶ In 2019, the data provided by Transport Topics showed a similar pattern based on the 28 companies that provided net income information, with an average profit margin of 5.8 percent.⁴⁷ It is uncertain whether the recent surge in net profit margin will continue through the analysis period, so FMCSA assumes the lower profit margin of 5 percent for motor carriers for purposes of this analysis.

Using the assumed profit margin of 5 percent for motor carriers, FMCSA estimates the revenue gained per hour

for motor carriers by multiplying the marginal cost per hour by the profit margin. This calculation results in a profit per hour of \$3.59.

Based on the loss of 50,446 driving hours, the Agency estimates motor carrier undiscounted opportunity costs at \$1.8 million over the 10-year analysis period (\$3.59 per hour × 50,446 hours × 10 years). The annualized cost is estimated at \$181,051. At a 7 percent discount rate, motor carrier opportunity costs are estimated at \$1.3 million over 10 years. The annualized cost is estimated at \$181,051.

Summary of the Estimated Cost of the Proposed Rule

Table 2 compares the total 10-year and annualized costs, both undiscounted and at a 7 percent discount rate. FMCSA estimates the total 10-year costs of this final rule at \$51.7 million undiscounted, and \$38.5 million discounted at 7 percent. Expressed on an annualized basis, this equates to \$5.2 million undiscounted, and \$5.5 million in costs at a 7 percent discount rate.

TABLE 2—TOTAL 10-YEAR AND ANNUALIZED COST OF THE FINAL RULE

Cost category	Undiscounted (2019 \$ million)		Discounted at 7% (\$ million)	
	10-Year total cost	Annualized	10-Year total cost	Annualized
SDLA Costs	\$30.1	\$3.0	\$23.1	\$3.3
AAMVA IT Cost	0.6	0.1	0.4	0.1
Federal Government IT Cost	2.8	0.3	2.2	0.3
Driver Opportunity Cost	16.4	1.6	11.5	1.6
Motor Carrier Opportunity Cost	1.8	0.2	1.3	0.2
Total	51.7	5.2	38.5	5.5

Benefits

The 2016 Clearinghouse final rule required States to request information from the Clearinghouse when processing specified licensing transactions. This final rule builds on that requirement by prohibiting SDLAs from issuing, renewing, upgrading, or transferring the CDL, or issuing, renewing, or upgrading the CLP, of any driver prohibited from operating a CMV due to drug and alcohol program violations. In addition, the rule requires SDLAs to downgrade the driver licenses of individuals prohibited from operating a CMV due to drug and alcohol program violations. SDLAs will rely on applicable State law and procedures to accomplish the downgrade and any subsequent reinstatement of the CLP or CDL privilege. FMCSA believes these requirements will improve highway safety by increasing the detection of CLP or CDL holders not qualified to operate a CMV due to a drug or alcohol program violation. The safety benefits attributable to the increased distribution of information about the driver’s prohibited status must be viewed in the context of the current regulatory scheme, as explained below.

The current CMV driving prohibition has been largely self-enforcing in that it

relies on motor carrier employers to prevent non-compliant drivers from operating. The Agency is aware, through motor carrier compliance reviews, targeted investigations, and other forms of retrospective compliance monitoring, that non-compliance with the driving prohibition occurs. Non-compliant drivers evade detection because, although subject to the driving prohibition, these drivers continue to hold a valid CLP or CDL in 47 States and the District of Columbia. Consequently, during a traffic stop or roadside inspection, traffic safety enforcement officers had no way of knowing the driver is not qualified to operate a CMV. The Clearinghouse changed that by making the information available to highway safety enforcement officers able to access the driver’s operating status in real time at roadside through FMCSA’s electronic enforcement tools, thereby increasing the detection of drivers not qualified to operate a CMV. MCSAP personnel can immediately place these drivers out of service.

The mandatory downgrade will further strengthen detection of drivers not qualified to operate due to a drug and alcohol program violation. The reason is that not all traffic safety

enforcement officers have reliable access to FMCSA’s electronic enforcement tools that, after the Clearinghouse became operational, made the driver’s prohibited status available at roadside. While the approximately 12,000 officers who are trained and certified under MCSAP have consistent roadside access to a CMV driver’s prohibited status, most of the approximately 500,000 non-MCSAP enforcement officers do not. Accordingly, if a driver subject to the prohibition holds a valid CLP or CDL at the time of a traffic stop, non-MCSAP personnel do not have access to the driver’s prohibited operating status. However, all traffic safety officers have access to the driver’s license status; a check of the license is conducted whenever there is a roadside intervention. Therefore, a driver whose license is downgraded due to a drug and alcohol program violation will be detected, through a routine license check, as not qualified to operate a CMV. The downgrade, by increasing the detection of individuals unlawfully driving a CMV, will therefore improve public safety.

Just as a driver’s prohibited status is not currently available to non-MCSAP officers, most SDLAs cannot currently

⁴⁶ Forbes. *Trucking Companies Hauling in Higher Sales*. Available at: <https://www.forbes.com/sites/sageworks/2018/03/04/trucking-companies->

[hauling-in-higher-sales/#40e0012f3f27](https://www.forbes.com/sites/sageworks/2018/03/04/trucking-companies-hauling-in-higher-sales/#40e0012f3f27) (accessed April 19, 2021).

⁴⁷ Transport Topics. 2019. *Top 100 For-Hire Carriers*. Available at: <https://www.ttnews.com/top100/for-hire/2019> (accessed April 19, 2021).

identify drivers who are subject to the prohibition. This rule will address this information gap by making the driver's prohibited status known to SDLAs at the time of a driver's requested licensing transaction. Under this approach, if the SDLA's mandated Clearinghouse query results in notice that the driver is subject to the CMV driving prohibition in § 382.501(a), the SDLA must not complete the transaction, resulting in non-issuance. This requirement will strengthen enforcement of the CMV prohibition by ensuring that these drivers complete RTD requirements before obtaining, renewing, transferring, or upgrading a CLP or CDL, as applicable.

The Agency anticipates that, by "raising the stakes" of non-compliance, the non-issuance and mandatory downgrade requirements will increase compliance with the CMV driving prohibition. As a result, FMCSA expects that some CLP and CDL holders will be deterred from the misuse of drugs or alcohol, though the Agency is unable to estimate the extent of deterrence.

Finally, this rule permits the Agency to use its enforcement resources more efficiently. Previously, FMCSA generally became aware that a driver was operating a CMV in violation of § 382.501(a) during the course of a compliance review of a motor carrier, or through a focused investigation of a carrier or service agent. The process for imposing sanctions on a driver who tested positive for a controlled substance, but continued to operate a CMV, is a lengthy one that involves outreach to the driver to determine whether RTD requirements have been met, issuance of a Notice of Violation, the driver's possible request for a hearing (and potentially a subsequent request for administrative review), and possible issuance of a Letter of Disqualification (LOD) to the driver, based on § 391.41(b)(12).⁴⁸ FMCSA may then forward the LOD to the SDLA, requesting that the driver's CDL be downgraded. Under current regulations, the SDLA is not obligated to comply with that request. The downgrade requirement obviates the need for this time-consuming and labor-intensive process, thus enabling the Agency's enforcement resources to be deployed more effectively.

B. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801, *et seq.*), the Office of

⁴⁸ Section 391.41(b)(12) applies only to the use of controlled substances; alcohol use, test refusals, and actual knowledge violations are not a basis for disqualification under this provision.

Information and Regulatory Affairs (OIRA) designated this rule as not a "major rule," as defined by 5 U.S.C. 804(2).⁴⁹

C. Regulatory Flexibility Act (*Small Entities*)

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601, *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121, 110 Stat. 857), requires Federal agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment. Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities and mandates that agencies strive to lessen any adverse effects on these entities. Consistent with SBREFA and DOT policy, FMCSA conducted an initial regulatory flexibility analysis (IRFA), published the analysis with the NPRM, and requested comments. FMCSA subsequently reviewed the available information on the number affected small entities and the impact of the rule on those small entities and presents the analysis and certification below.

Affected Small Entities

The term *small entities* means small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. This rule will impact States, AAMVA, drivers, motor carriers, and FMCSA. Under the standards of the RFA, as amended, States are not small entities because they do not meet the definition of a small entity in section 601 of the RFA. Specifically, States are not small governmental jurisdictions under section 601(5) of the RFA, both because State government is not among the various levels of government listed in section 601(5), and because, even if this were the case, no State, including the District of Columbia, has a population of less than 50,000, which is the criterion

⁴⁹ A "major rule" means any rule that the Administrator of OIRA at OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of \$100 million or more; (b) a major increase in costs or prices for consumers, individual industries, Federal agencies, State agencies, local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 804(2)).

to be a small governmental jurisdiction under section 601(5) of the RFA.

CLP and CDL holders are not considered small entities because they do not meet the definition of a small entity in Section 601 of the RFA. Specifically, these drivers are considered neither a small business under Section 601(3) of the RFA nor a small organization under Section 601(4).

Under the RFA, as amended, motor carriers may be considered small entities based on the SBA-defined size standards used to classify entities as small. SBA establishes separate standards for each industry, as defined by the North American Industry Classification System (NAICS).⁵⁰ This rule could affect motor carriers in many different industry sectors in addition to the Transportation and Warehousing sector (NAICS sectors 48 and 49); for example, the Construction sector (NAICS sector 23), the Manufacturing sector (NAICS sectors 31, 32, and 33), and the Retail Trade sector (NAICS sectors 44 and 45). Industry groups within these sectors have size standards for qualifying as small based on the number of employees (*e.g.*, 500 employees), or on the amount of annual revenue (*e.g.*, \$27.5 million in revenue). Not all entities within these industry sectors will be impacted by this rule, and therefore FMCSA cannot determine the number of small entities based on the SBA size standards. However, it is plausible to estimate that if each affected driver worked for a distinct motor carrier, a maximum of 5,045 motor carriers would be impacted by this rule annually. The 2020 Pocket Guide to Large Truck and Bus Statistics estimates that there were approximately 603,000 interstate motor carriers and intrastate hazardous materials motor carriers in 2019.⁵¹ Therefore, this rule could impact a maximum of 0.84 percent of interstate motor carriers and intrastate hazardous materials motor carriers. FMCSA does not consider 0.84 percent to be a substantial number of small entities.

Impact

Motor carriers may incur opportunity costs as a result of this rule if a driver employed by a given motor carrier is

⁵⁰ Executive Office of the President, OMB. "North American Industry Classification System." 2017. Available at: https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf (Accessed July 24, 2020).

⁵¹ U.S. Department of Transportation, Federal Motor Carrier Safety Administration. "2020 Pocket Guide to Large Truck and Bus Statistics" October 2020. Available at: <https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2020-10/FMCSA%20Pocket%20Guide%202020-v8-FINAL-10-29-2020.pdf> (accessed on October 30, 2020).

subject to reinstatement and is ineligible to resume safety-sensitive functions, such as driving, until the SDLA restores the CLP or CDL privilege to the driver's license. In order to determine if this impact would be significant, FMCSA considers the impact as a percentage of annual revenue and estimates the impact to be significant if it surpasses one percent of revenue. For each affected driver, the motor carrier will incur an opportunity cost of \$36 (\$3.59 × 10 hours). The motor carrier would need to have annual revenue below \$3,589 (\$36 ÷ 0.01) in order for this impact to reach the threshold of significance. It is not possible to determine the maximum number of drivers that would be affected at a given motor carrier in any one year. For illustrative purposes, FMCSA depicts the impact if a motor carrier employed 15 affected drivers. The annual opportunity cost would be \$538 (\$3.59 × 10 hours × 15 drivers), and the motor carrier would need to have annual revenues of \$53,835 for the impact to be considered significant. FMCSA considers it unlikely that a motor carrier would be able to operate with such low revenues in light of the sizeable expenses to own and maintain CMVs, and support employees. The impact of this rule increases linearly with the number of affected drivers (*i.e.*, for each affected driver, the impact increases by \$36 per year), and as such, FMCSA does not anticipate that this rule will result in a significant impact on small motor carriers regardless of the number of affected drivers per motor carrier.

Therefore, I hereby certify that this rule will not have a significant impact on a substantial number of small entities.

D. Assistance for Small Entities

In accordance with section 213(a) of SBREFA, FMCSA wants to assist small entities in understanding this final rule so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman (Office of the National Ombudsman, see <https://www.sba.gov/about-sba/>

oversight-advocacy/office-national-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 FMCSA, call 1-888-REG-FAIR (1-888-734-3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

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 \$168 million (which is the value equivalent of \$100 million in 1995, adjusted for inflation to 2019 levels) or more in any one year. Though this final rule would not result in such an expenditure, the Agency does discuss the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act (Collection of Information)

This final rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The information collection requirements established in the 2016 final rule were approved under OMB Control Number 2126-0057. Notwithstanding any other provision of law, no person is required to respond to a collection of information unless that collection displays a valid OMB control number.

G. E.O. 13132 (Federalism)

A rule has implications for federalism if, pursuant to Section 1(a) of E.O. 13132, it has "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." FMCSA analyzed this final rule under that Order and determined that it has implications for federalism. A summary of the impact of federalism in this rule follows.

MAP-21 (49 U.S.C. 31306a(l)(1) and (2)) expressly preempts State laws and regulations pertaining to CDL holders who have violated drug and alcohol program requirements that are inconsistent with Section 31306a or Federal regulations implementing Section 31306a. Section 31306a(l)(2)

specifies that State-based requirements pertaining to the reporting of violations of FMCSA's drug and alcohol use and testing program are included within the scope of the preemption set forth in subparagraph (1). MAP-21 excepts from preemption State laws and regulations relating to an action taken on the CDL of a driver who violates FMCSA's drug and alcohol program (49 U.S.C. 31306a(l)(3)). The impact of these statutory provisions on the States is discussed in Section V. as noted below.

In addition, this final rule establishes minimum requirements for the issuance of CLPs and CDLs by the States, consistent with the Agency's authority under 49 U.S.C. 31308 and 31305(a). Though the Agency's CDL regulations in 49 CFR parts 383 and 384 impact the States, they do not directly preempt any State law or regulation. In order to avoid having amounts withheld from their Highway Trust Fund apportionment, States participating in the CDL program must substantially comply with the requirements of 49 U.S.C. 31311(a), as defined in 49 CFR 384.301, and must annually certify substantial compliance as set forth in 49 CFR 384.305. States determined by FMCSA to be in substantial non-compliance are subject to withholding of a portion of the State's Highway Trust Fund apportionment in accordance with 49 U.S.C. 31314 and 49 CFR 384.401.

In accordance with section 6(c)(2) of E.O. 13132, the Agency's federalism summary impact statement, set forth below, describes FMCSA's prior consultation with State officials, summarizes their concerns and the Agency's position supporting the need to issue the final rule, and addresses the extent to which the concerns of State officials have been met.

Federalism Summary Impact Statement

In accordance with sections 4(e) and 6(c)(1) of E.O. 13132, FMCSA consulted with the National Governors Association, the National Conference of State Legislatures, and AAMVA early in the process of developing this rule to gain insight into the federalism implications of regulations implementing the MAP-21 requirements. The States' representatives requested that the rule delineate the States' role and responsibilities regarding the Clearinghouse, as well as the potential cost implications for the States, as clearly as possible and in a manner consistent with congressional intent. They also requested that the preemptive effect of MAP-21 on existing State laws requiring the reporting of FMCSA's drug and alcohol program violation to the

SDLA be specifically discussed, and that FMCSA allow States the time they need to enact laws or regulations implementing Federal regulatory requirements related to the Clearinghouse. AAMVA recommended that the Agency disqualify drivers who commit drug or alcohol violations, which would provide SDLAs a clear basis on which to take action on the commercial license. Additionally, prior to issuance of the NPRM, the Agency consulted directly with the SDLAs during FMCSA's CDL Roundtable, a bimonthly forum convened to discuss regulatory developments. Following publication of the NPRM, FMCSA presented an overview of the proposal to SDLAs participating in AAMVA's CDLIS Working Group and encouraged the States to submit comments to the rulemaking docket.

Drivers who violate FMCSA's drug and alcohol program and continue to operate a CMV despite the existing prohibition pose a significant risk to public safety. The Agency believes the final rule is necessary in order to mitigate that risk. By requiring States receiving MCSAP grant funds to adopt the CMV driving prohibition, and requiring that States, to avoid having Federal highway funds withheld under 49 U.S.C. 31314, deny certain commercial licensing transactions and remove the commercial driving privileges of drivers prohibited from operating a CMV due to drug and alcohol program violations, the final rule will improve safety by keeping prohibited drivers off our Nation's highways.

The final rule addresses the questions and concerns of the States, as noted above, in Section II., subsections A. (Purpose and Summary of the Regulatory Action), B. (Summary of Major Provisions), and C. (Costs and Benefits); Section IV. (Legal Basis for the Rulemaking); Section V., subsections A. (Purpose and Intent of State-Related Clearinghouse Requirements), B. (AAMVA's Petition for Rulemaking), and C. (Impact of MAP-21 on State Laws); Section VI., subsection B. (Comments and Responses); Section XI., subsection A. (E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures); and in relevant portions of the regulatory text.⁵²

⁵² For more detailed information regarding questions and concerns raised about the extent and nature of the States' role in the Clearinghouse, and the preemptive effect of MAP-21 on State-based reporting requirements, see the NPRM (85 FR 23670), located in docket FMCSA-2017-0330 accessible at www.regulations.gov.

H. Privacy

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108-447, 118 Stat. 2809, 3268, note following 5 U.S.C. 552a), requires the Agency to conduct a Privacy Impact Assessment of a regulation that will affect the privacy of individuals. The assessment considers impacts of the rule on the privacy of information in an identifiable form and related matters. The FMCSA Privacy Officer has evaluated the risks and effects the rulemaking might have on collecting, storing, and sharing personally identifiable information and has evaluated protections and alternative information handling processes in developing the rule to mitigate potential privacy risks. FMCSA preliminarily determined that this rule would not require the collection of individual personally identifiable information beyond that which is already required by the Clearinghouse final rule.

In addition, the Agency submitted a Privacy Threshold Assessment analyzing the rulemaking and the specific process for collection of personal information to the DOT, Office of the Secretary's Privacy Office. The DOT Privacy Office has determined that this rulemaking does not create privacy risk.

The E-Government Act of 2002, Public Law 107-347, sec. 208, 116 Stat. 2899, 2921 (Dec. 17, 2002), requires Federal agencies to conduct a Privacy Impact Assessment for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information because of this final rule.

I. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 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.

J. National Environmental Policy Act of 1969

FMCSA analyzed this rule pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined this action is categorically

excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, March 1, 2004), Appendix 2, paragraph (6)(t)(2). The categorical exclusion (CE) in paragraph (6)(t)(2) covers regulations ensuring States comply with the Commercial Motor Vehicle Act of 1986, by having the appropriate information technology systems concerning the qualification and licensing of persons who apply for and persons who are issued a CDL. The requirements in this rule are covered by this CE, and this action does not have the potential to significantly affect the quality of the environment.

List of Subjects

49 CFR Part 382

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

49 CFR Part 384

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 392

Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

For the reasons discussed in this preamble, FMCSA amends 49 CFR parts 382, 383, 384, 390, and 392 as follows:

PART 382—CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

- 1. The authority citation for part 382 is revised to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31301 *et seq.*, 31502; sec. 32934 of Pub. L. 112-141, 126 Stat. 405, 830; and 49 CFR 1.87.

- 2. Amend § 382.503 by:
 - a. Revising the section heading;
 - b. Designating the text as paragraph (a); and
 - c. Adding paragraph (b).

The revision and addition read as follows:

§ 382.503 Required evaluation and testing, reinstatement of commercial driving privilege.

* * * * *

(b) No driver whose commercial driving privilege has been removed from the driver's license, pursuant to § 382.501(a), shall drive a commercial motor vehicle until the State Driver Licensing Agency reinstates the CLP or CDL privilege to the driver's license.

■ 3. Amend § 382.717 by revising paragraph (a)(2)(i) to read as follows:

§ 382.717 Procedures for correcting information in the database.

(a) * * *
(2) * * *

(i) Petitioners may request that FMCSA add documentary evidence of a non-conviction to an employer's report of actual knowledge that the driver received a traffic citation for driving a commercial motor vehicle while under the influence of alcohol or controlled substances if the citation did not result in a conviction. For the purposes of this section, conviction has the same meaning as used in 49 CFR part 383.

* * * * *

■ 4. Amend § 382.725 by revising paragraphs (a) and (b) to read as follows:

§ 382.725 Access by State licensing authorities.

(a)(1) Before November 18, 2024, in order to determine whether a driver is qualified to operate a commercial motor vehicle, the chief commercial driver's licensing official of a State may obtain the driver's record from the Clearinghouse if the driver has applied for a commercial driver's license or commercial learner's permit from that State.

(2) On or after November 18, 2024, in order to determine whether a driver is qualified to operate a commercial motor vehicle, the chief commercial driver's licensing official of a State must obtain the driver's record from the Clearinghouse if the driver has applied for a commercial driver's license or commercial learner's permit from that State.

(b) By applying for a commercial driver's license or a commercial learner's permit, a driver is deemed to have consented to the release of information from the Clearinghouse in accordance with this section.

* * * * *

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 5. The authority citation for part 383 is revised to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 *et seq.*, and 31502; secs. 214 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 1012(b) of Pub. L. 107–56, 115 Stat. 272, 297, sec. 4140 of Pub. L. 109–59, 119 Stat. 1144, 1746; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; and 49 CFR 1.87.

■ 6. Amend § 383.5 by revising paragraph (4) of the definition of “CDL downgrade” to read as follows:

§ 383.5 Definitions.

* * * * *

CDL downgrade * * *

(4) A State removes the CLP or CDL privilege from the driver's license.

* * * * *

■ 7. Amend § 383.73 by:

- a. Adding paragraph (a)(3);
- b. Revising paragraphs (b)(10), (c)(10), (d)(9), (e)(8), and (f)(4); and
- c. Adding paragraph (q).

The additions and revisions read as follows:

§ 383.73 State procedures.

(a) * * *

(3) Beginning November 18, 2024, the State must request information from the Drug and Alcohol Clearinghouse, and if, in response to the request, the State receives notification that pursuant to § 382.501(a) of this chapter the applicant is prohibited from operating a commercial motor vehicle, the State must not issue, renew, or upgrade the CLP. If the applicant currently holds a CLP issued by the State, the State must also comply with the procedures set forth in paragraph (q) of this section.

(b) * * *

(10) Beginning November 18, 2024, the State must request information from the Drug and Alcohol Clearinghouse. If, in response to that request, the State receives notification that pursuant to § 382.501(a) of this chapter the applicant is prohibited from operating a commercial motor vehicle, the State must not issue the CDL.

* * * * *

(c) * * *

(10) Beginning November 18, 2024, the State must request information from the Drug and Alcohol Clearinghouse. If, in response to that request, the State receives notification that pursuant to § 382.501(a) of this chapter the applicant is prohibited from operating a commercial motor vehicle, the State must not transfer the CDL.

(d) * * *

(9) Beginning November 18, 2024, the State must request information from the Drug and Alcohol Clearinghouse. If, in response to that request, the State receives notification that pursuant to § 382.501(a) of this chapter the applicant is prohibited from operating a

commercial motor vehicle, the State must not renew the CDL or H endorsement and must comply with the procedures set forth in paragraph (q) of this section.

(e) * * *

(8) Beginning November 18, 2024, the State must request information from the Drug and Alcohol Clearinghouse. If, in response to that request, the State receives notification that pursuant to § 382.501(a) of this chapter the applicant is prohibited from operating a commercial motor vehicle, the State must not issue an upgrade of the CDL and must comply with the procedures set forth in paragraph (q) of this section.

* * * * *

(f) * * *

(4) Beginning November 18, 2024, the State must request information from the Drug and Alcohol Clearinghouse. If, in response to that request, the State receives notification that pursuant to § 382.501(a) of this chapter the applicant is prohibited from operating a commercial motor vehicle, the State must not issue, renew, transfer or upgrade a non-domiciled CLP or CDL and must comply with the procedures set forth in paragraph (q) of this section, as applicable.

* * * * *

(q) *Drug and Alcohol Clearinghouse.* Beginning November 18, 2024, the State must, upon receiving notification that pursuant to § 382.501(a) of this chapter, the CLP or CDL holder is prohibited from operating a commercial motor vehicle, initiate established State procedures for downgrading the CLP or CDL. The downgrade must be completed and recorded on the CDLIS driver record within 60 days of the State's receipt of such notification.

(1) *Termination of downgrade process when the driver is no longer prohibited.* If, before the State completes and records the downgrade on the CDLIS driver record, the State receives notification that pursuant to § 382.503(a) of this chapter the CLP or CDL holder is no longer prohibited from operating a commercial motor vehicle, the State must, if permitted by State law, terminate the downgrade process without removing the CLP or CDL privilege from the driver's license.

(2) *Reinstatement after FMCSA notification that the driver is no longer prohibited.* If, after the State completes and records the downgrade on the CDLIS driver record, FMCSA notifies the State that pursuant to § 382.503(a) of this chapter a driver is no longer prohibited from operating a commercial motor vehicle, the State must make the driver eligible for reinstatement of the

CLP or CDL privilege to the driver's license, if permitted by State law.

(3) *Reinstatement after Clearinghouse error correction.* If, after the State completes and records the downgrade on the CDLIS driver record, FMCSA notifies the State that the driver was erroneously identified as prohibited from operating a commercial motor vehicle, the State shall:

(i) Reinstatement the CLP or CDL privilege to the driver's license as expeditiously as possible; and

(ii) Expunge from the CDLIS driver record and, if applicable, the motor vehicle record, as defined in § 390.5T of this chapter, any reference related to the driver's erroneous prohibited status.

PART 384—STATE COMPLIANCE WITH COMMERCIAL DRIVER'S LICENSE PROGRAM

■ 8. The authority citation for part 384 is revised to read as follows:

Authority: 49 U.S.C. 31136, 31301, *et seq.*, and 31502; secs. 103 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1753, 1767; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 5524 of Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 9. Amend § 384.225 by adding paragraph (a)(3) to read as follows:

§ 384.225 CDLIS driver recordkeeping.

(a) * * *

(3) The removal of the CLP or CDL privilege from the driver's license in accordance with § 383.73(q) of this chapter.

* * * * *

■ 10. Revise § 384.235 to read as follows:

§ 384.235 Commercial driver's license Drug and Alcohol Clearinghouse.

Beginning November 18, 2024, the State must:

(a) Request information from the Drug and Alcohol Clearinghouse in accordance with § 383.73 of this chapter and comply with the applicable provisions therein; and

(b)(1) Comply with § 383.73(q) of this chapter upon receiving notification from FMCSA that, pursuant to § 382.501(a) of this chapter, the driver is prohibited from operating a commercial motor vehicle; and

(2) Comply with § 383.73(q) of this chapter upon receiving notification from FMCSA that, pursuant to § 382.503(a) of this chapter, the driver is no longer prohibited from operating a commercial motor vehicle; or that FMCSA erroneously identified the driver as prohibited from operating a commercial motor vehicle.

■ 11. Amend § 384.301 by adding paragraph (o) to read as follows:

§ 384.301 Substantial compliance—general requirements.

* * * * *

(o) A State must come into substantial compliance with the requirements of subpart B of this part and part 383 of this chapter in effect as of November 8, 2021, as soon as practicable, but, unless otherwise specifically provided in this part, not later than November 18, 2024.

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 12. The authority citation for part 390 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31134, 31136, 31137, 31144, 31149, 31151, 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; secs. 212 and 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as added and transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743; sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; secs. 32101(d) and 32934, Pub. L. 112–141, 126 Stat. 405, 778, 830; sec. 2, Pub. L. 113–125, 128 Stat. 1388; secs. 5403, 5518, and 5524, Pub. L. 114–94, 129 Stat. 1312, 1548, 1558, 1560; sec. 2, Pub. L. 115–105, 131 Stat. 2263; and 49 CFR 1.87.

■ 13. Amend § 390.3 as follows:

- a. Lift the suspension of the section;
- b. Revise paragraph (f)(1); and
- c. Suspend the section indefinitely.

§ 390.3 General applicability.

* * * * *

(f) * * *

(1) All school bus operations as defined in § 390.5, except for §§ 391.15(e) and (f), 392.15, 392.80, and 392.82 of this chapter;

* * * * *

■ 14. Amend § 390.3T by revising paragraph (f)(1) to read as follows:

§ 390.3T General applicability.

* * * * *

(f) * * *

(1) All school bus operations as defined in § 390.5T, except for §§ 391.15(e) and (f), 392.15, 392.80, and 392.82 of this chapter;

* * * * *

PART 392—DRIVING OF COMMERCIAL MOTOR VEHICLES

■ 15. The authority citation for part 392 is revised to read as follows:

Authority: 49 U.S.C. 504, 13902, 31136, 31151, 31502; Section 112 of Pub. L. 103–311, 108 Stat. 1673, 1676 (1994), as amended by sec. 32509 of Pub. L. 112–141, 126 Stat. 405–805 (2012); and 49 CFR 1.87.

■ 16. Add § 392.15 to read as follows:

§ 392.15 Prohibited driving status.

No driver, who holds a commercial learner's permit or a commercial driver's license, shall operate a commercial motor vehicle if prohibited by § 382.501(a) of this subchapter.

Issued under authority delegated in 49 CFR 1.87.

Meera Joshi,

Deputy Administrator.

[FR Doc. 2021–21928 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 210929–0200]

RIN 0648–BH65

Pacific Island Fisheries; Modifications to the American Samoa Longline Fishery Limited Entry Program

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

ACTION: Final rule.

SUMMARY: This final rule implements Amendment 9 to the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP). It modifies the American Samoa longline fishery limited entry program to consolidate vessel class sizes, modify permit eligibility requirements, and reduce the minimum harvest requirements for small vessels. This final rule also makes several housekeeping changes to the program's regulations. The intent of this rule is to reduce regulatory barriers that may be limiting small vessel participation in the fishery, and provide for sustained community and American Samoan participation in the fishery.

DATES: The final rule is effective November 8, 2021.

ADDRESSES: Copies of Amendment 9, including an environmental analysis and Regulatory Impact Review, and other supporting documents for this action are available at <https://www.regulations.gov/document/NOAA-NMFS-2018-0023-0001>.

Written comments and recommendations for the information collection contained in this final rule may be submitted to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818, and to www.reginfo.gov/public/do/PRAMain.

FOR FURTHER INFORMATION CONTACT: Kate Taylor, NMFS PIR Sustainable Fisheries, 808-725-5182.

SUPPLEMENTARY INFORMATION: The Western Pacific Fishery Management Council (Council) and NMFS manage the American Samoa longline fishery under the FEP and implementing Federal regulations. The fishery is currently limited to 60 permits distributed over four vessel size classes. Permits are valid for three years, and issued only to individuals who meet specific eligibility criteria. A permit holder must also meet minimum landing requirements within three years to renew the permit. Existing requirements have created programmatic barriers that may be hampering small vessel participation in the fishery. As described in Amendment 9, the Council recommended changes to the program that will reduce complexity and provide for sustained community participation in the small vessel American Samoa deep-set longline fishery. This final rule implements the new provisions established by Amendment 9, as follows:

- Consolidate four existing vessel sizes classes into two, *i.e.*, small (less than 50 ft (15.2 m)) and large (equal to or larger than 50 ft (15.2 m));
- Permit holders must be U.S. citizens or nationals. Applicants do not need to document a history of participation to be eligible for a permit, but if there is competition between applicants, NMFS will continue to use a priority ranking system based on earliest documented history of fishing in a vessel class size;
- Permits may be transferred only among U.S. citizens or nationals. There is no requirement for documented participation in the fishery to receive a transferred permit;
- The small vessel minimum harvest requirement is now 500 lb (227 kg) of pelagic management unit species (MUS) within a 3-year period. (The large vessel harvest requirement remains 5,000 lb (2,268 kg) over three years);
- The minimum harvest amount must be landed in American Samoa within a 3-year permit period. These required harvests need not be caught within the U.S. exclusive economic zone (EEZ) around American Samoa;
- Permits are valid for the same, fixed 3-year period as the 3-year period required to make a minimum harvest; and
- When a permit is transferred, the minimum harvest period does not restart. If the minimum amount has not been caught at the time of transfer, the new permit owner is required to meet

the harvest requirement based on the following formula: The product of percentage of time left within the 3-year permit period and the minimum harvest amount.

You may find additional background information on this action in the preamble to the proposed rule (86 FR 37982, July 19, 2021).

Comments and Responses

On June 30, 2021, NMFS published the notice of availability (NOA) for Amendment 9 and request for public comments (86 FR 34711); the comment period ended August 30, 2021. The American Samoa Department of Marine and Wildlife Resources provided comments on Amendment 9 that generally supported the changes established by the Council, and offered to work with NMFS on future reporting and permitting issues in this and other fisheries.

On July 19, 2021, NMFS published a proposed rule and request for public comments (86 FR 37982); the comment period ended September 2, 2021. NMFS received comments from the Hawaii Longline Association (HLA), and responds below.

Comment 1: HLA noted that two dozen Hawaii vessels also hold American Samoa longline permits. Although the fishery is operating safely during the Covid-19 pandemic, HLA is concerned that a minimum landing requirement would force these dual-permitted vessels to land in American Samoa, possibly spreading the virus to an area that has been largely virus-free. HLA requested that NMFS delay the effectiveness of the landing requirement and associated 3-year period for large vessels until the threat caused by the pandemic has eased.

Response: The American Samoa Department of Health has health and safety protocols in place that are applicable to fishing vessels landing in the territory. During the pandemic, U.S. fishing vessels have continued to land in American Samoa under these requirements, which include proof of a negative Covid-19 test, evidence of having recovered from Covid-19 in the past six months, or proof of complete vaccination at least 14 days prior to the arrival. Anyone arriving in port must provide the documentation at least 72 hours prior to arrival. Prior approval is required for crew to disembark. Quarantine measures are also in place, as needed, for vessels entering the port.

These protocols have been effective. To date, there has been only one documented Covid-19 case in American Samoa. Based on the effective health and safety protocols in place there,

NMFS does not agree that a delay in effectiveness for the minimum harvest landing requirements for large vessels is warranted.

Changes From the Proposed Rule

This final rule does not make any substantive changes from the proposed rule.

This rule does make three administrative housekeeping changes. The first revises 50 CFR 665.14 relating to reporting. After NMFS published the proposed rule for this action, we published a separate final rule that requires electronic reporting for American Samoa Class C and D vessels (86 FR 42744, August 5, 2021). Because this final rule replaces the former C and D classes with a single large vessel class, we are updating § 665.14 to clarify that large vessels must report electronically.

The second modifies 50 CFR 665.802(x) relating to observer coverage. In the proposed rule, we erred in using the term “large vessel,” which is a vessel equal to or greater than 50 ft long. If implemented, we would have inadvertently removed the requirement for a vessel between 40 and 50 ft to carry an observer. In Amendment 9, the Council did not recommend removal of the observer coverage requirement for vessels between 40 and 50 ft in length overall (LOA), and this final rule correctly implements the Council’s intention by replacing “large vessel” with “vessel greater than 40 ft (12.2 m) LOA” in § 665.802(x).

The third housekeeping changes are in 50 CFR 665.816, relating to permit validity. Amendment 9 established a requirement that the duration of a permit is three years from the date of issuance and that the term of the permit validity does not change or reset in the event of a permit transfer. To accurately implement the recommendations in Amendment 9, this rule adds a new § 665.816(f) that clarifies that a permit is valid for three years. The rule also clarifies in § 665.816(h)(1) and (3) the 3-year permit term and that it does not change in the event of a transfer.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Fishery and Conservation Act, the NMFS Assistant Administrator has determined that this final rule is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable law.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic

impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. NMFS did not receive any comments regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

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

This final rule contains a change to a collection of information requirement for the purposes of the Paperwork Reduction Act (PRA). This rule revises the existing requirements for the collection of information under OMB Control Number 0648–0490 Pacific Islands Permit Family of Forms by modifying the type of permit issued in the American Samoa longline fishery limited entry program. Changes required under this rule applicable to the PRA include the consolidation of the four current permit size classes (Class A, B, C, and D) into two permit class sizes (small and large), the restriction of permit eligibility to U.S. citizens, U.S. nationals, and U.S. companies, partnerships, or corporations, and the elimination of the requirement to have documented history of participation in the fishery to be eligible for a permit. These changes require revising the permit application form. In the proposed rule published in the **Federal Register** for a 45-day comment period, NMFS indicated our intent to revise this information collection (86 FR 37982, July 19, 2021). The revision is not expected to affect the number of respondents or anticipated responses or to effect the number of burden hours and burden cost to fishermen. The public reporting burden for completing an American Samoa longline fishery permit application is estimated to average 1.25 hours per response, including the time for reviewing instructions, gathering the data needed, and submitting the permit application.

We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Written comments and recommendations for this information collection should be submitted on the following website: www.reginfo.gov/public/do/PRAMain. Find this particular information collection by using the search function and entering either the title of the collection or the OMB Control Number 0648–0490.

Notwithstanding any other provisions of the law, no person is required to

respond or, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 665

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Longline, Pacific Islands.

Dated: September 29, 2021.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 665 as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 1. The authority citation for 50 CFR part 665 continues to read as follows:

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

■ 2. In § 665.12, add the definition of “Small vessel” in alphabetical order to read as follows:

§ 665.12 Definitions.

* * * * *

Small vessel means, as used in this part, any vessel less than 50 ft (15.2 m) in length overall.

* * * * *

■ 3. In § 665.14, revise paragraph (b)(1)(ii)(A) to read as follows:

§ 665.14 Reporting and recordkeeping.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) The operator of a fishing vessel subject to the requirements of § 665.801(b) or a large vessel subject to the requirements of § 665.801(c) must maintain on board the vessel an accurate and complete record of catch, effort, and other data electronically using a NMFS-certified electronic logbook, and must record and transmit electronically all information specified by the Regional Administrator within 24 hours after the completion of each fishing day.

* * * * *

■ 4. In § 665.19, revise paragraph (a)(2) to read as follows:

§ 665.19 Vessel monitoring system.

(a) * * *

(2) American Samoa large vessel longline limited entry permit issued pursuant to § 665.801(c);

* * * * *

■ 5. In § 665.802, revise paragraph (x) to read as follows:

§ 665.802 Prohibitions.

* * * * *

(x) Fail to comply with a term or condition governing the observer program established in § 665.808, if using a vessel registered for use with a Hawaii longline limited access permit, or a vessel greater than 40 ft (12.2 m) LOA registered for use with an American Samoa longline limited access permit to fish for western Pacific pelagic MUS using longline gear.

* * * * *

■ 6. Revise § 665.816 to read as follows:

§ 665.816 American Samoa longline limited entry program.

(a) *General.* Under § 665.801(c), certain U.S. vessels are required to be registered for use under a valid American Samoa longline limited access permit. Under the American Samoa Longline Limited Entry Program, the maximum number of longline fishing permits available is limited to 60 permits annually.

(b) *Terminology.* For purposes of this section, the following terms have these meanings:

(1) *Documented participation* means participation proved by, but not necessarily limited to, a properly submitted NMFS or American Samoa logbook, an American Samoa creel survey record, a delivery or payment record from an American Samoa-based cannery, retailer or wholesaler, an American Samoa tax record, an individual wage record, ownership title, vessel registration, or other official documents showing:

(i) Ownership of a vessel that was used to fish in the EEZ around American Samoa; or

(ii) Evidence of work on a fishing trip during which longline gear was used to harvest western Pacific pelagic MUS in the EEZ around American Samoa. If the applicant does not possess the necessary documentation of evidence of work on a fishing trip based on records available only from NMFS or the Government of American Samoa (*e.g.*, creel survey record or logbook), the applicant may issue a request to PIRO to obtain such records from the appropriate agencies, if available. The applicant should provide sufficient information on the fishing trip to allow PIRO to retrieve the records.

(2) *Family* means those people related by blood, marriage, and formal or informal adoption.

(c) *Vessel size classes.* The Regional Administrator shall issue American Samoa longline limited access permits in the following size classes:

(1) Small vessel, which is less than 50 ft (15.2 m) LOA.

(2) Large vessel, which is equal to or over 50 ft (15.2 m) LOA.

(d) *Permit eligibility.* Any U.S. national or U.S. citizen or company, partnership, or corporation is eligible for an American Samoa longline limited access permit.

(e) *Permit issuance.* (1) If the number of permits issued falls below the maximum number of permits allowed, the Regional Administrator shall publish a notice in the **Federal Register** and use other means to notify prospective applicants of any available permit(s) in each class. Any application for issuance of a permit must be submitted to PIRO no later than 120 days after the date of publication of the notice on the availability of additional permits in the **Federal Register**. The Regional Administrator shall issue permits to persons according to the following priority standard:

(i) Priority accrues to the person with the earliest documented participation in the pelagic longline fishery in the EEZ around American Samoa from smallest to largest vessel.

(ii) In the event of a tie in the priority ranking between two or more applicants, the applicant whose second documented participation in the pelagic longline fishery in the EEZ around American Samoa is first in time will be ranked first in priority. If there is still a tie between two or more applicants, the Regional Administrator will select the successful applicant by an impartial lottery.

(2) An application must be made, and application fees paid, in accordance with § 665.13(c)(1), (d), and (f)(2). If the applicant is any entity other than a sole owner, the application must be accompanied by a supplementary information sheet, obtained from the Assistant Regional Administrator for Sustainable Fisheries, containing the names and mailing addresses of all owners, partners, and corporate officers that comprise ownership of the vessel for which the permit application is prepared.

(3) Within 30 days of receipt of a completed application, the Assistant Regional Administrator for Sustainable Fisheries shall make a decision on

whether the applicant qualifies for a permit and will notify the successful applicant by a dated letter. The successful applicant must register a vessel of appropriate size to the permit within 120 days of the date of the letter of notification. The successful applicant must also submit a supplementary information sheet, obtained from the Assistant Regional Administrator for Sustainable Fisheries, containing the name and mailing address of the owner of the vessel to which the permit is registered. If the registered vessel is owned by any entity other than a sole owner, the names and mailing addresses of all owners, partners, and corporate officers must be included. If the successful applicant fails to register a vessel to the permit within 120 days of the date of the letter of notification, the Assistant Regional Administrator for Sustainable Fisheries shall issue a letter of notification to the next person on the priority list or, in the event that there are no more prospective applicants on the priority list, re-start the issuance process pursuant to paragraph (e)(1) of this section. Any person who fails to register the permit to a vessel under this paragraph (e)(3) within 120 days shall not be eligible to apply for a permit for 6 months from the date those 120 days expired.

(4) An appeal of a denial of an application for a permit shall be processed in accordance with § 665.801(o).

(f) *Permit term.* The duration of a permit is three years from the date of issuance by NMFS.

(g) *Permit transfer.* The holder of an American Samoa longline limited access permit may transfer the permit to another individual, partnership, corporation, or other entity as described in this section. The application for permit transfer must be submitted to the Regional Administrator within 30 days of the transfer date. If the applicant is any entity other than a sole owner, the application must be accompanied by a supplementary information sheet, obtained from the Assistant Regional Administrator for Sustainable Fisheries, containing the names and mailing addresses of all owners, partners, and corporate officers. After such an application has been made, the permit

is not valid for use by the new permit holder until the Regional Administrator has issued the permit in the new permit holder's name under § 665.13(c).

(1) An American Samoa longline limited access permit may be transferred (by sale, gift, bequest, intestate succession, barter, or trade) to only the following persons:

(i) A western Pacific community located in American Samoa that meets the criteria set forth in section 305(I)(2) of the Magnuson-Stevens Act, 16 U.S.C. 1855(I)(2), and its implementing regulations in this part; or

(ii) Any U.S. citizens or national.

(2) Additionally, an American Samoa longline limited access small vessel permit may also be transferred (by sale, gift, bequest, intestate succession, barter, or trade) to a family member of the permit holder.

(h) *Permit renewal.* (1) An American Samoa longline limited access permit will not be renewed following three years in which the vessel(s) to which it is registered landed less than:

(i) Small vessel: A total of 500 lb (227 kg) of western Pacific pelagic MUS harvested using longline gear; or

(ii) Large vessel: A total of 5,000 lb (2,268 kg) of western Pacific pelagic MUS harvested using longline gear.

(2) For all vessels, the minimum harvest amount must be landed in American Samoa.

(3) In the event of a transfer, the new permit holder would be required to meet the harvest requirement based on the following formula: Remaining harvest amount = product of percentage of time left within the 3-year permit period and the minimum harvest amount for that size vessel. The original permit term and duration does not change in the event of a transfer.

(i) *Concentration of permits.* No more than 10 percent of the maximum number of permits, of both size classes combined, may be held by the same permit holder. Fractional interest will be counted as a full permit for calculating whether the 10-percent standard has been reached.

(ii) [Reserved]

[FR Doc. 2021-21662 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 86, No. 192

Thursday, October 7, 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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0845; Project Identifier MCAI-2021-00651-T]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A330-200, -300, -800, and -900 series airplanes; and Model A340-200, -300, -500, and -600 series airplanes. This proposed AD was prompted by reports that the instructions on the doghouse door lock placard are unclear and incomplete. This proposed AD would require replacing the placard with an improved instruction placard, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. This proposed AD would also prohibit the installation of affected parts under certain conditions. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 22, 2021.

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

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

- *Fax:* 202-493-2251.

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

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this material on the EASA website at <https://ad.easa.europa.eu>. You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0845.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0845; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3229; email vladimir.ulyanov@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2021-0845; Project Identifier MCAI-2021-00651-T" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3229; email vladimir.ulyanov@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021-0136, dated June 4, 2021 (EASA AD 2021-0136) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS A330-201, A330-202, A330-203, A330-223, A330-243, A330-301, A330-302, A330-303, A330-321, A330-322, A330-323, A330-341, A330-342, A330-343, A330-841, A330-941, A340-211, A340-212, A340-213, A340-311, A340-312, A340-313, A340-541, A340-542, A340-642, and A340-643 airplanes. Model A340-542 and A340-643 airplanes are not certificated by the FAA and are not included on the U.S.

type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by reports of unclear and incomplete door lock handling instructions for the door of the passenger cabin doghouse, which contains emergency equipment intended to minimize the effects of survivable accidents.

The FAA is proposing this AD to address possible incorrect operation of the doghouse door lock due to unclear and incomplete handling instructions on the door placard installed near the lock. This condition, if not addressed, could lead to failure of the latch, which could block the door in the closed position and prevent access to the emergency equipment inside the doghouse.

See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0136 specifies procedures for replacing the instruction placard on the passenger cabin doghouse door. EASA AD 2021–0136 also prohibits the installation of doghouses with incorrect instruction placards.

This material is reasonably available because the interested parties have access to it through their normal course

of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0136 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA

ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0136 by reference in the FAA final rule. This proposed AD would therefore require compliance with EASA AD 2021–0136 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0136 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2021–0136. Service information required by EASA AD 2021–0136 for compliance will be available at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0845 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 62 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × \$85 per hour = \$170	Up to \$95 per placard	Up to \$265 per placard	Up to \$16,430.*

* Assuming one placard per product. The number of placards on an airplane depends on the passenger configuration and varies from operator to operator.

Authority for This Rulemaking

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

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

develop on products identified in this rulemaking action.

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2021–0845; Project Identifier MCAI–2021–00651–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 22, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS airplanes, certificated in any category, as identified in paragraphs (c)(1) through (8) of this AD.

(1) Model A330–201, –202, –203, –223, and –243 airplanes.

(2) Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(3) Model A330–841 airplanes.

(4) Model A330–941 airplanes.

(5) Model A340–211, –212, and –213 airplanes.

(6) Model A340–311, –312, and –313 airplanes.

(7) Model A340–541 airplanes.

(8) Model A340–642 airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports that the instructions on the doghouse door lock placard are unclear and incomplete. The FAA is issuing this AD to address possible incorrect operation of the doghouse door lock due to unclear and incomplete handling instructions on the door placard installed near the lock. This condition, if not addressed, could lead to failure of the latch, which could block the door in the closed position and prevent access to the emergency equipment inside the doghouse.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0136, dated June 4, 2021 (EASA AD 2021–0136).

(h) Exceptions to EASA AD 2021–0136

(1) Where EASA AD 2021–0136 refers to its effective date, this AD requires using the effective date of this AD.

(2) Although EASA AD 2021–0136 specifies to “remove the placard and install an improved handling instructions placard on each affected part,” this AD requires replacing the placard on each affected part with an improved handling instructions placard.

(3) The “Remarks” section of EASA AD 2021–0136 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, 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 responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) For EASA AD 2021–0136, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; Internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>. You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0845.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229; email vladimir.ulyanov@faa.gov.

(3) For service information identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone

+49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this material on the EASA website at <https://ad.easa.europa.eu>. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on September 30, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–21832 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2021–0870; Project Identifier MCAI–2021–00644–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A300 series airplanes. This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 22, 2021.

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

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room

W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver to mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this IBR material on the EASA website at <https://ad.easa.europa.eu>. You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0870.

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–2021–0870; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email dan.rodina@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2021–0870; Project Identifier MCAI–2021–00644–T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments

received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email dan.rodina@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0134, dated June 1, 2021 (EASA AD 2021–0134) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus SAS Model A300 series airplanes.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to prevent reduced structural integrity of the airplane. See the MCAI for additional background information.

EASA previously issued EASA AD 2017–0207, dated October 12, 2017 (EASA AD 2017–0207), and EASA AD 2020–0110R1, dated May 27, 2020 (EASA AD 2020–0110R1), requiring the actions described in the Airbus A300 ALS, Part 2, Revision 03, and Variation 3.1, respectively. EASA AD 2017–0207 corresponds to FAA AD 2018–19–17, Amendment 39–19417 (83 FR 48207, September 24, 2018) and EASA AD 2020–0110R1 corresponds to certain

actions in FAA AD 2020–23–11, Amendment 39–21327 (85 FR 75838, November 27, 2020). Since those EASA ADs were issued, Airbus published the Variation, as defined in EASA AD 2021–0134, which reduces the limit of validity (LOV) for Model A300 airplanes. This variation will be incorporated into the Airbus A300 ALS, Part 2, at the next revision. EASA AD 2021–0134 does not supersede EASA AD 2017–0207 and EASA AD 2020–0110R1.

For the reason described above, this AD requires compliance with the reduced LOV as specified in the variation.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0134 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination and Requirements of This Proposed AD

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

Proposed AD Requirements

This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2021–0134 described previously, as incorporated by reference. Any differences with EASA AD 2021–0134 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions. Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the

revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j)(1) of this proposed AD.

As described in FAA Advisory Circular 120–104 (http://www.faa.gov/documentLibrary/media/Advisory_Circular/120-104.pdf), several programs have been developed to support initiatives that will ensure the continued airworthiness of aging airplane structure. The last element of those initiatives is the requirement to establish a LOV of the engineering data that support the structural maintenance program under 14 CFR 26.21. This proposed AD is the result of an assessment of the previously established programs by the design approval holder (DAH) during the process of establishing the LOV for the affected airplanes. The actions specified in this proposed AD are necessary to complete certain programs to ensure the continued airworthiness of aging airplane structure and to support an airplane reaching its LOV.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0134 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0134 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0134 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2021–0134. Service information required by EASA AD 2021–0134 for compliance will be available at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0870 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (e.g., inspections), intervals, or critical design configuration control limitations (CDCCLs) may be used unless the actions, intervals, and CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in the AMOCs paragraph under “Other FAA Provisions.” This new format includes a “New Provisions for Alternative Actions, Intervals, and CDCCLs” paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action, interval, or CDCCL.

Costs of Compliance

The FAA estimates that this proposed AD affects 1 airplane of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be \$7,650 (90 work-hours × \$85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2021–0870; Project Identifier MCAI–2021–00644–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 22, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to prevent reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0134, dated June 1, 2021 (EASA AD 2021–0134).

(h) Exceptions to EASA AD 2021–0134

(1) Where EASA AD 2021–0134 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (1) of EASA AD 2021–0134 specifies “This AD invalidates the LOV as specified in Airbus A300 ALS Part 2 Revision 03 [EASA AD 2017–0207],” this AD replaces the LOVs specified in paragraph 1.3 of Airbus A300 ALS, Part 2, Revision 03, dated March 16, 2021, as required by FAA AD 2018–19–17, Amendment 39–19417 (83 FR 48207, September 24, 2018).

(3) Paragraph (2) of EASA AD 2021–0134 specifies revising “the approved AMP” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The “Remarks” section of EASA AD 2021–0134 does not apply to this AD.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals are allowed unless they are

approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2021–0134.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, 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 Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2020–0210, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; Internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>. You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. 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–2021–0870.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and

fax 206–231–3225; email dan.rodina@faa.gov.

Issued on October 1, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–21831 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2021–0812; Airspace Docket No. 19–AAL–71]

RIN 2120–AA66

Proposed Amendment of United States Area Navigation (RNAV) Route T–267; Nome, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend United States Area Navigation (RNAV) route T–267 in the vicinity of Nome, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Comments must be received on or before November 22, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0812; Airspace Docket No. 19–AAL–71 at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

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

FOR FURTHER INFORMATION CONTACT:

Christopher McMullin, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV in Alaska and improve the efficient flow of air traffic within the National Airspace System (NAS) by lessening the dependency on ground based navigation.

Comments Invited

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

Communications should identify both docket numbers (FAA Docket No. FAA-2021-0812; Airspace Docket No. 19-AAL-71) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at <https://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2021-0812; Airspace Docket No. 19-AAL-71." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking

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

Availability of NPRM

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2003, Congress enacted the Vision 100-Century of Aviation Reauthorization Act (Pub. L., 108-176), which established a joint planning and development office in the FAA to manage the work related to the Next Generation Air Transportation System (NextGen). Today, NextGen is an ongoing FAA-led modernization of the nation's air transportation system to make flying safer, more efficient, and more predictable.

In support of NextGen, this proposal is part of a larger and comprehensive T-route modernization project in the state of Alaska. The project mission statement states: "To modernize Alaska's Air

Traffic Service route structure using satellite based navigation Development of new T-routes and optimization of existing T-routes will enhance safety, increase efficiency and access, and will provide en route continuity that is not subject to the restrictions associated with ground based airway navigation." As part of this project, the FAA evaluated the existing Colored Airway structure for: (a) Direct replacement (*i.e.*, overlay) with a T-route that offers a similar or lower Minimum En route Altitude (MEA) or Global Navigation Satellite System Minimum En route Altitude (GNSS MEA); (b) the replacement of the colored airway with a T-route in an optimized but similar geographic area, while retaining similar or lower MEA; or (c) removal with no route structure (T-route) restored in that area because the value was determined to be insignificant.

The aviation industry/users have indicated a desire for the FAA to transition the Alaskan en route navigation structure away from dependency on Non-Directional Beacons (NDB), and move to develop and improve the RNAV route structure. The FAA proposes to amend segments of RNAV route T-267. The amendments would include extending the airway to the north beyond the current termination point to provide alternate routing for two colored airways (B-3, and G-18), while also including RNAV reference points for two NDB's (Atkasuk, AK (ATK), and Noatak, AK (OQK)) scheduled to be decommissioned. Additionally the proposed extension of the airway would provide instrument approach connectivity to Noatak airport, AK (PAWN) and access to Red Dog airport (PADG) via SICOV WP. The proposed amendments would provide for lower MEAs while also ensuring that the appropriate route criteria is met along the entire route.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend RNAV route T-267 in the vicinity of Nome, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. The proposed route changes are described below.

T-267: T-267 currently extends from Nome (OME), AK to Kotzebue (OTZ), AK. The FAA proposes to extend the route north from OTZ to provide alternate navigation for Colored airways B-3 and G-18. The rest of the route would remain unchanged.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F dated August 10,

2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document would be published subsequently in the Order.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory

evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration

proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T-267 Nome, AK to ZISDU, AK [Amend]

NOME, AK (OME)	VOR/DME	(Lat. 64°29'06.39" N, long. 165°15'11.43" W)
BALIN, AK	WP	(Lat. 66°33'54.54" N, long. 161°34'32.45" W)
KOTZEBUE, AK (OTZ)	VOR/DME	(Lat. 66°53'08.46" N, long. 162°32'23.77" W)
SICOV, AK	WP	(Lat. 67°20'44.42" N, long. 162°49'58.62" W)
NWIAF, AK	WP	(Lat. 67°42'21.09" N, long. 162°29'30.89" W)
BTURN, AK	WP	(Lat. 68°14'34.30" N, long. 163°06'13.70" W)
PODKE, AK	WP	(Lat. 68°59'30.64" N, long. 163°07'52.26" W)
JODGU, AK	WP	(Lat. 69°44'11.33" N, long. 162°59'46.66" W)
ZISDU, AK	WP	(Lat. 70°28'08.64" N, long. 157°25'38.98" W)

* * * * *

Issued in Washington, DC, on September 30, 2021.

Michael R. Beckles,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021-21813 Filed 10-6-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2021-0813; Airspace Docket No. 19-AAL-74]

RIN 2120-AA66

Proposed Amendment of United States Area Navigation (RNAV) Route T-275; Bethel, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend United States Area Navigation (RNAV) route T-275 in the vicinity of Bethel, AK in support of a large and

comprehensive T-route modernization project for the state of Alaska.

DATES: Comments must be received on or before November 22, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590; telephone: 1(800) 647-5527, or (202) 366-9826. You must identify FAA Docket No. FAA-2021-0813; Airspace Docket No. 19-AAL-74 at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>. FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at https://www.faa.gov/air_traffic/publications/. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email:

fr.inspection@nara.gov or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

FOR FURTHER INFORMATION CONTACT: Christopher McMullin, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

dependency on ground based navigation.

Comments Invited

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

Communications should identify both docket numbers (FAA Docket No. FAA-2021-0813; Airspace Docket No. 19-AAL-74) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at <https://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2021-0813; Airspace Docket No. 19-AAL-74." The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRM

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during

normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2003, Congress enacted the Vision 100-Century of Aviation Reauthorization Act (Pub L., 108-176), which established a joint planning and development office in the FAA to manage the work related to the Next Generation Air Transportation System (NextGen). Today, NextGen is an ongoing FAA-led modernization of the nation's air transportation system to make flying safer, more efficient, and more predictable.

In support of NextGen, this proposal is part of a larger and comprehensive T-route modernization project in the state of Alaska. The project mission statement states: "To modernize Alaska's Air Traffic Service route structure using satellite based navigation Development of new T-routes and optimization of existing T-routes will enhance safety, increase efficiency and access, and will provide en route continuity that is not subject to the restrictions associated with ground based airway navigation." As part of this project, the FAA evaluated the existing Colored Airway structure for: (a) Direct replacement (*i.e.*, overlay) with a T-route that offers a similar or lower Minimum En route Altitude (MEA) or Global Navigation Satellite System Minimum En route Altitude (GNSS MEA); (b) the replacement of the colored airway with a T-route in an optimized but similar geographic area, while retaining similar or lower MEA; or (c) removal with no route structure (T-route) restored in that area because the value was determined to be insignificant.

The aviation industry/users have indicated a desire for the FAA to transition the Alaskan en route navigation structure away from dependency on Non-Directional Beacons (NDB), and move to develop and improve the RNAV route structure.

The FAA proposes to amend RNAV route T-275 by extending it to the south to provide an alternate routing for Colored airway B-7. B-7 utilizes Oscarville, AK, (OSE) and Cape Newenham, AK, (EHM) NDBs, which are on the scheduled decommission list. Additionally, the proposed amendments would provide for lower MEAs while also ensuring that the appropriate route criteria is met along the entire route.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend RNAV route T-275 in the vicinity of Bethel, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. The proposed route changes are described below.

T-275: T-275 currently extends from Bethel, AK, (BET) to Unalakleet, AK, (UNK). The FAA proposes to extend the route south from BET to provide alternate navigation for Colored airway B-7. The segment between BET and UNK would also change adding an additional turn point, taking the airway slightly to the west to allow for better route connectivity with proposed and current T-routes.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document would be published subsequently in the Order.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

T-275 ZIKNI, AK to Unalakleet, AK [Amended]

ZIKNI, AK	WP	(Lat. 58°39'21.69" N, long. 162°04'25.48" W)
BETHEL, AK (BET)	VORTAC	(Lat. 60°47'05.41" N, long. 161°49'27.59" W)
DAVBE, AK	WP	(Lat. 61°50'52.64" N, long. 161°30'41.89" W)
UNALAKLEET, AK (UNK)	VOR/DME	(Lat. 63°53'30.99" N, long. 160°41'03.39" W)

* * * * *

Issued in Washington, DC, on September 30, 2021.

Michael R. Beckles,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021-21861 Filed 10-6-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[REG-107707-21]

RIN 1545-BQ02

Requirements Related to Surprise Billing; Part II

AGENCY: Internal Revenue Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Treasury (Treasury Department) and Internal Revenue Service (IRS) are proposing regulations that provide for a federal independent dispute resolution (IDR) process to permit group health plans and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under 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

The Proposed Amendment

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

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

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

Management (OPM), the Employee Benefits Security Administration of the Department of Labor (DOL), and the Center for Medicare & Medicaid Services 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 December 6, 2021.

Applicability date: It is proposed that these regulations apply for plan years beginning on or after January 1, 2022.

ADDRESSES: In commenting, please refer to file code REG-107707-21. Comments, including mass comment submissions, must be submitted in one of the following two 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 mail.* You may mail written comments to the following address **ONLY:** Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-5653, Washington, DC 20210, Attention: RIN 1210-AB00.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Kari DiCecco, (202) 317-5500, Internal Revenue Service, Department of the Treasury.

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

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 propose to amend paragraphs (a), (c), (d), and (g) of § 54.9815-2719 of the Miscellaneous Excise Tax Regulations to expand the scope of claims eligible for external review to include adverse benefit determinations related to compliance with the surprise billing and cost-sharing protections under the No Surprises Act.

The Treasury Department and the IRS also propose to add §§ 54.9816-8 and 54.9817-2 to establish a federal IDR process that nonparticipating providers or facilities, nonparticipating providers of air ambulance services, and group health plans may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services.

The temporary regulations published elsewhere in this issue of the **Federal Register** add §§ 54.9815-2719T, 54.9816-8T, and 54.9817-2T. 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 54.9815–2719 is amended by revising paragraphs (a), (c), (d), and (g) to read as follows:

§ 54.9815–2719 Internal claims and appeals and external review processes.

[The text of proposed § 54.9815–2719(a), (c), (d), and (g) is the same as the text of § 54.9815–2719T(a), (c), (d), and (g) published elsewhere in this issue of the **Federal Register**].

■ Par. 3. Section 54.9816–1 is added to read as follows:

[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**].

■ Par. 4. Section 54.9816–2(a) and (b) is added to read as follows:

[The text of proposed § 54.9816–2(a) and (b) is the same as the text of § 54.9816–2T(a) and (b) published elsewhere in this issue of the **Federal Register**].

■ Par. 5. Sections 54.9816–8 and 54.9817–2 are added to read as follows:

§ 54.9816–8 Independent dispute resolution process.

[The text of proposed § 54.9816–8 is the same as the text of § 54.9816–8T published elsewhere in this issue of the **Federal Register**].

§ 54.9817–2 Independent dispute resolution process for air ambulance services.

[The text of proposed § 54.9817–2 is the same as the text of § 54.9817–2T published elsewhere in this issue of the **Federal Register**].

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2021–21419 Filed 9–30–21; 4:15 pm]

BILLING CODE 4830–01–P

COUNCIL ON ENVIRONMENTAL QUALITY

40 CFR Parts 1502, 1507, and 1508

[CEQ–2021–0002]

RIN 0331–AA05

National Environmental Policy Act Implementing Regulations Revisions

AGENCY: Council on Environmental Quality.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Council on Environmental Quality (CEQ) is proposing to modify certain aspects of its regulations for implementing the procedural provisions of the National Environmental Policy Act (NEPA) to generally restore regulatory provisions that were in effect for decades before being modified in 2020. CEQ proposes these changes in order to better align the provisions with CEQ's extensive experience implementing NEPA, in particular its perspective on how NEPA can best inform agency decision making, as well as longstanding Federal agency experience and practice, NEPA's statutory text and purpose, including making decisions informed by science, and case law interpreting NEPA's requirements. The proposed rule would restore provisions addressing the purpose and need of a proposed action, agency NEPA procedures for implementing CEQ's NEPA regulations, and the definition of "effects." CEQ invites comments on the proposed revisions.

DATES:

Comments: CEQ must receive comments by November 22, 2021.

Public meeting: CEQ will conduct two online public meetings for the proposed rule on Tuesday, October 19, 2021, from 1 to 4 p.m. EDT, and Thursday, October 21, 2021 from 5 to 8 p.m. EDT. To register for the meetings, please visit CEQ's website at www.nepa.gov.

ADDRESSES: You may submit comments, identified by docket number CEQ–

2021–0002, by any of the following methods:

■ **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

■ **Fax:** 202–456–6546.

■ **Mail:** Council on Environmental Quality, 730 Jackson Place NW, Washington, DC 20503.

Instructions: All submissions received must include the agency name, "Council on Environmental Quality," and docket number, CEQ–2021–0002, for this rulemaking. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. Do not submit electronically any information you consider to be private, Confidential Business Information (CBI), or other information, the disclosure of which is restricted by statute.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Amy B. Coyle, Deputy General Counsel, 202–395–5750, Amy.B.Coyle@ceq.eop.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 1, 1970, President Nixon signed into law the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.* Congress enacted NEPA by a unanimous vote in the Senate and a nearly unanimous vote in the House¹ to declare a national policy to promote environmental protection for present and future generations. NEPA was established to "encourage productive and enjoyable harmony" between humans and the environment; to promote efforts that will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of people; and to enrich the understanding of the ecological systems and natural resources important to the Nation. 42 U.S.C. 4321.

To achieve these objectives, NEPA makes it the continuing policy of the Federal Government to use all practicable means and measures to create and maintain conditions under which humans and nature can exist in productive harmony and fulfill the social, economic, and other requirements of present and future

¹ See Linda Luther, Cong. Rsch. Serv., RL33152, The National Environmental Policy Act: Background and Implementation (2008), <https://crsreports.congress.gov/product/details?prodcode=RL33152>.

generations of Americans. 42 U.S.C. 4331. NEPA directs Federal agencies to prepare “detailed statements,” referred to as environmental impact statements (EISs), for “major Federal actions significantly affecting the quality of the human environment.” 42 U.S.C. 4332(2)(C). NEPA established the Council on Environmental Quality (CEQ) in the Executive Office of the President, which advises the President on environmental policy matters and oversees Federal agencies’ implementation of NEPA. 42 U.S.C. 4342. In many respects, NEPA was a statute ahead of its time, and it remains relevant and vital today, from its statements that decisions be grounded in science to its recognition that sustainability and a livable environment are fundamental to social and economic well-being. *See, e.g.*, 42 U.S.C. 4331, 4332(A).

In 1970, President Nixon issued Executive Order (E.O.) 11514, *Protection and Enhancement of Environmental Quality*, which directed CEQ to issue guidelines for implementation of section 102(2)(C) of NEPA.² In response, CEQ issued interim guidelines in April 1970, and revised the guidelines in 1971 and 1973.³ In 1977, President Carter issued E.O. 11991, *Relating to Protection and Enhancement of Environmental Quality*, amending E.O. 11514 and directing CEQ to issue regulations to govern implementation of NEPA and requiring that Federal agencies comply with those regulations.⁴ CEQ promulgated implementing procedures in 1978 at 40 CFR parts 1500 through 1508.⁵ The regulations, issued 8 years after NEPA’s enactment, reflect CEQ’s interpretation of and expertise in NEPA, initial interpretations of the courts, and Federal agency experience implementing NEPA. Consistent with the requirement in 40 CFR 1507.3, Federal agencies, in turn, issue and update their own implementing procedures to supplement CEQ’s procedures and integrate the NEPA process into the agencies’ specific programs and processes. Agencies consult with CEQ in the development of these procedures to ensure that their agency-specific procedures are consistent with CEQ’s regulations. CEQ made technical amendments to the 1978

implementing regulations in 1979⁶ and amended one provision in 1986,⁷ but it left the regulations largely unchanged for over 40 years (1978 NEPA Regulations). As a result, CEQ and Federal agencies have extensive experience in implementing NEPA and the 1978 regulations, and a large body of agency practice and case law has developed based on the CEQ NEPA regulations that remained in substantially the same form from 1978 to 2020. The fundamental principles of informed and science-based decision making, transparency, and public engagement are reflected in both the NEPA statute and CEQ’s 1978 NEPA Regulations, and it is those core principles that CEQ seeks to advance in this proposed rule.

On August 15, 2017, President Trump issued E.O. 13807, *Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects*,⁸ which, in part, directed CEQ to establish and lead an interagency working group to identify and propose changes to the NEPA regulations.⁹ In response, on January 10, 2020, CEQ published a notice of proposed rulemaking (NPRM) proposing broad revisions to the 1978 NEPA Regulations.¹⁰ A wide range of stakeholders submitted more than 1.1 million comments on the proposed rule,¹¹ including state and local governments, Tribes, environmental advocacy organizations, professional and industry associations, and other advocacy or non-profit organizations. Many commenters provided detailed feedback on the legality, policy wisdom, and potential consequences of the proposed amendments. In keeping with the proposed rule, the final rule promulgated on July 16, 2020, made wholesale revisions to the regulations and took effect on September 14, 2020 (2020 NEPA Regulations or 2020 Rule).¹²

In the months that followed the issuance of the 2020 NEPA Regulations, five lawsuits were filed challenging the 2020 Rule.¹³ These cases challenge the

2020 NEPA Regulations on a variety of grounds, including under the Administrative Procedure Act (APA), NEPA, and the Endangered Species Act, contending that the rule exceeded CEQ’s authority and that the related rulemaking process was procedurally and substantively defective. In response to CEQ and joint motions, the district courts have issued temporary stays in each of these cases, except for *Wild Virginia v. Council on Environmental Quality*, which the district court dismissed without prejudice on June 21, 2021,¹⁴ and is currently on appeal to the U.S. Court of Appeals for the Fourth Circuit.

On January 20, 2021, President Biden issued E.O. 13990, *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*.¹⁵ Section 1 of E.O. 13990 establishes an Administration policy to listen to the science; improve public health and protect our environment; ensure access to clean air and water; limit exposure to dangerous chemicals and pesticides; hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; reduce greenhouse gas emissions; bolster resilience to the impacts of climate change; restore and expand our national treasures and monuments; and prioritize both environmental justice and the creation of well-paying union jobs necessary to deliver these goals.¹⁶

Section 2 of the E.O. calls for Federal agencies to review existing regulations issued between January 20, 2017, and January 20, 2021, for consistency with the policy articulated in the E.O. and to take appropriate action. Section 7(b) revokes a number of E.O.s, including E.O. 13807, and section 7(f) directs agencies to promptly take steps to rescind any rules or regulations implementing or enforcing any of the revoked E.O.s. An accompanying White House fact sheet, published on January

Council on Env’t Quality, No. 3:20cv5199 (N.D. Cal. 2020); *California v. Council on Env’t Quality*, No. 3:20cv06057 (N.D. Cal. 2020); *Iowa Citizens for Cmty. Improvement v. Council on Env’t Quality*, No. 1:20cv02715 (D.D.C. 2020). Additionally, in *The Clinch Coalition v. U.S. Forest Service*, No. 2:21cv00003 (W.D. Va. 2020), plaintiffs challenge the U.S. Forest Service’s NEPA implementing procedures, which established new categorical exclusions, and, relatedly, the 2020 Rule’s provisions on categorical exclusions.

¹⁴ *Wild Va. v. Council on Env’t Quality*, No. 3:20cv45, 2021 WL 2521561 (W.D. Va. June 21, 2021).

¹⁵ 86 FR 7037 (Jan. 25, 2021).

¹⁶ *Id.*, sec. 1.

² 35 FR 4247 (Mar. 7, 1970), sec. 3(h).

³ *See* 35 FR 7390 (May 12, 1970) (interim guidelines); 36 FR 7724 (Apr. 23, 1971) (final guidelines); 38 FR 10856 (May 2, 1973) (proposed revisions to the guidelines); 38 FR 20550 (Aug. 1, 1973) (revised guidelines).

⁴ 42 FR 26967 (May 25, 1977).

⁵ 43 FR 55978 (Nov. 23, 1978).

⁶ 44 FR 873 (Jan. 3, 1979).

⁷ 51 FR 15618 (Apr. 25, 1986) (amending 40 CFR 1502.22).

⁸ 82 FR 40463 (Aug. 24, 2017).

⁹ *Id.*, sec. 5(e)(iii).

¹⁰ 85 FR 1684 (Jan. 10, 2020).

¹¹ *See* Docket No. CEQ–2019–0003, <https://www.regulations.gov/document/CEQ-2019-0003-0001>.

¹² 85 FR 43304 (July 16, 2020).

¹³ *Wild Va. v. Council on Env’t Quality*, No. 3:20cv45 (W.D. Va. 2020); *Env’t. Justice Health All. v. Council on Env’t Quality*, No. 1:20cv06143 (S.D.N.Y. 2020); *Alaska Cmty. Action on Toxics v.*

20, 2021, specifically directs CEQ to review the 2020 NEPA Regulations for consistency with E.O. 13990's objectives.¹⁷

On January 27, 2021, the President signed E.O. 14008, *Tackling the Climate Crisis at Home and Abroad*, which establishes a government-wide approach to the climate crisis by reducing greenhouse gas emissions and an Administration policy to increase climate resilience, transition to a clean-energy economy, address environmental justice and invest in disadvantaged communities, and spur well-paying union jobs and economic growth.¹⁸ E.O. 14008 also requires the Chair of CEQ and the Director of the Office of Management and Budget (OMB) to ensure that Federal infrastructure investments reduce climate pollution and that Federal permitting decisions consider the effects of greenhouse gas emissions and climate change.¹⁹

II. CEQ's Approach to Revising the 2020 NEPA Regulations

Consistent with E.O. 13990 and E.O. 14008, CEQ is engaged in a comprehensive review of the 2020 NEPA Regulations to ensure that they provide for sound and efficient environmental review of Federal actions, including those actions integral to tackling the climate crisis, in a manner that enables meaningful public participation, respects Tribal sovereignty, protects our Nation's resources, and promotes better environmental and community outcomes. CEQ proposes regulatory changes in this NPRM to enhance clarity on NEPA implementation, to better effectuate NEPA's statutory requirements and purposes, to ensure that Federal decisions are guided by science, to better protect and enhance the quality of the human environment, and to provide full and fair processes that inform the public about the environmental effects of government actions and enable public participation.

CEQ's review of the 2020 NEPA Regulations and the proposed regulatory amendments are guided by CEQ's and Federal agencies' extensive experience implementing NEPA for the last 50 years. As part of its oversight role, CEQ reviews every agency's proposed new or updated NEPA implementing procedures. As part of this iterative process, CEQ engages with agencies to

understand their specific authorities and programs to ensure consideration of environmental impacts is integrated into their decision-making processes. Additionally, where necessary or appropriate, CEQ engages with agencies on NEPA reviews for specific projects or project types. For example, CEQ has convened interagency working groups to ensure efficient and effective environmental reviews for transportation and broadband projects. CEQ also has extensive experience providing written guidance to Federal agencies on a wide range of NEPA-related issues, including environmental justice, emergency response activities, climate change, and more.²⁰ And, CEQ meets regularly with external stakeholders to understand their perspectives on the NEPA process. Finally, CEQ coordinates with other Federal agencies and components of the White House on a wide array of environmental issues that also arise in the NEPA context, such as endangered species consultation or impacts to Federal lands and waters from federally permitted activities.

It is CEQ's view that the 2020 NEPA Regulations may have the effect of limiting the scope of NEPA analysis, with negative repercussions for environmental protection and environmental quality, including in critical areas such as climate change and environmental justice. Portions of the 2020 NEPA Regulations also may not reflect NEPA's statutory purposes to "encourage productive and enjoyable harmony" between humans and the environment, promote efforts that will prevent or eliminate damage to the environment and biosphere, and enhance public health and welfare. *See* 42 U.S.C. 4321. Some changes introduced by the 2020 NEPA Regulations also may not support science-based decision making or be compatible with the Administration's policies to improve public health, protect the environment, prioritize environmental justice, provide access to clean air and water, and reduce greenhouse gas emissions that contribute to climate change.²¹

To address these concerns, CEQ is engaging in a series of rulemakings to propose revisions to the 2020 NEPA Regulations. As a preliminary step, CEQ issued an interim final rule on June 29, 2021, amending the requirement in 40 CFR 1507.3(b) for agencies to propose

changes to their existing NEPA supplemental procedures by September 14, 2021, in order to make their procedures consistent with the 2020 NEPA Regulations.²² CEQ extended the date by two years to avoid having agencies propose changes to their implementing procedures on a tight deadline to conform to a rule that is undergoing extensive review and will likely change in the near future.

CEQ intends to reconsider and revise the 2020 NEPA Regulations using a phased approach. This NPRM initiates a "Phase 1" rulemaking to focus on a discrete set of provisions. In identifying what provisions to address in Phase 1, CEQ focused on the provisions that (1) pose significant near-term interpretation or implementation challenges for Federal agencies and would have the most impact to agencies' NEPA processes during the interim period before a "Phase 2" rulemaking is complete; (2) make sense to revert to the 1978 regulatory approach for the reasons discussed in Part III of this preamble; and (3) CEQ is generally unlikely to propose to further revise in a Phase 2 rulemaking. Further, because CEQ recently received comments on these exact provisions through the rulemaking process for the 2020 NEPA Regulations, CEQ has the benefit of voluminous public comments on these issues, which CEQ considered in the development of this proposed rule. In Phase 2, CEQ intends to issue a second NPRM to more broadly revisit the 2020 NEPA Regulations and propose further revisions to ensure that the NEPA process provides for efficient and effective environmental reviews that are consistent with the statute's text and purpose; provides regulatory certainty to Federal agencies; promotes better decision making consistent with NEPA's statutory requirements; and meets environmental, climate change, and environmental justice objectives.

III. Summary of Proposed Rule

As discussed in this section, CEQ proposes three revisions to the 2020 NEPA Regulations in this Phase 1 rulemaking: (1) To eliminate language in the description of purpose and need for a proposed action when it is an agency's statutory duty to review applications for authorization (40 CFR 1502.13) and make a conforming edit to the definition of "reasonable alternatives" (40 CFR 1508.1(z)); (2) to remove limitations on agency NEPA procedures for implementing CEQ's NEPA Regulations (40 CFR 1507.3); and (3) to return to the definitions of "effects" in the prior,

¹⁷ White House Fact Sheet: List of Agency Actions for Review (Jan. 20, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/>.

¹⁸ 86 FR 7619 (Feb. 1, 2021).

¹⁹ *Id.*, sec. 213(a).

²⁰ *See* <https://www.energy.gov/nepa-ceq-guidance-documents> for a list of current CEQ guidance documents.

²¹ *See* E.O. 13990, *supra* note 15, and E.O. 14008, *supra* note 18.

²² 86 FR 34154 (June 29, 2021).

longstanding 1978 NEPA Regulations (40 CFR 1508.1(g)).

CEQ proposes to amend these provisions by generally reverting to the language from the 1978 NEPA Regulations that was in effect for more than 40 years, subject to minor revisions for clarity. In proposing to revert to language in the 1978 Regulations, this NPRM addresses issues similar or identical to those the public and Federal agencies recently had the opportunity to consider and comment on during the rulemaking for the 2020 NEPA Regulations, which will facilitate an expeditious Phase 1 rulemaking. For each provision described in this section, CEQ provides a high-level summary of some of the significant issues raised in these public comments, which CEQ considered in the development of this proposed rule.

A. Purpose and Need (§ 1502.13)

The purpose and need section of an EIS sets forth the rationale for the agency's proposed action. Development of the purpose and need is a vital early step in the NEPA process that is foundational to other elements of a NEPA review. For example, the purpose and need statement sets the parameters for the range of reasonable alternatives an agency considers and informs the scope of effects that an agency must analyze in an EIS. The 1978 NEPA Regulations required that each EIS briefly state the underlying purpose and need to which the agency is responding in proposing the alternatives, including the proposed action. The 2020 NEPA Regulations modified this provision by adding language that requires agencies to base the purpose and need on the goals of an applicant and the agency's authority when the agency's statutory duty is to review an application for authorization. The 2020 NEPA Regulations also made a conforming addition to the definition of "reasonable alternatives" to carry over the new language on purpose and need. Here, CEQ proposes in § 1502.13 to revert to the language of the 1978 NEPA Regulations for purpose and need and conform the definition of "reasonable alternatives" in § 1508.1(z) to this change.

CEQ proposes this change because the language added by the 2020 NEPA Regulations requires an agency to always base the purpose and need on the goals of an applicant and the agency's statutory authority when an agency is reviewing an application for authorization. This language could be construed to require agencies to prioritize the applicant's goals over other relevant factors, including the

public interest. CEQ does not consider this approach to reflect the best reading of the NEPA statute or lay the appropriate groundwork for environmentally sound decision making. Agencies should have discretion to base the purpose and need for their actions on a variety of factors, which include the goals of the applicant, but not to the exclusion of other factors. For example, agencies may consider regulatory requirements, desired conditions on the landscape or other environmental outcomes, and local economic needs, as well as an applicant's goals. Always tailoring the purpose and need to an applicant's goals when considering a request for an authorization could prevent an agency from considering alternatives that better meet the policies and responsibilities set forth in NEPA merely because they do not meet an applicant's stated goals. Additionally, an applicant's goals themselves could be potentially confusing or unduly narrow or restrictive. Restoring the 1978 language would eliminate this confusing language and reaffirm agency discretion to develop and rely on statements of purpose and need that are consistent with the agency's decision-making responsibilities while considering multiple relevant factors, including the public interest and the goals of an applicant. This restoration would confirm that agencies should consider a range of alternatives that are technically and economically feasible and meet the purpose and need for the proposed action but that are not unreasonably constrained by an applicant's stated goals.

In adding this language, the preamble to the 2020 Rule explained that CEQ intended to clarify that when an agency is responsible for reviewing applications for authorizations, the agency *must* base the purpose and need on the applicant's goals and the agency's statutory authority, citing *Citizens Against Burlington, Inc. v. Busey*, 938 F.2d 190, 196 (D.C. Cir. 1991). However, this case did not require the agency to base the purpose and need on the applicant's goals; rather, the court held that the agency's consideration of the applicant's goals to develop the purpose and need statement was not arbitrary and capricious. However, the court did not require that the applicant's goals be the sole (or even primary) factor in the formulation of the purpose and need for the action. *See id.* at 196–99.

CEQ proposes to remove the reference to the agency's statutory authority because it is unnecessary and confusing. It is unnecessary because agencies already had a long history of developing

purpose and need statements under the 1978 NEPA Regulations guided by their statutory authority and the scope of the agency decision under consideration. The reference is confusing because it implies that an agency's authority is only relevant when an agency proposes to grant an authorization, and agencies must also appropriately consider the scope of their authority when evaluating other agency actions, including those that do not involve specific authorizations. Therefore, CEQ proposes to eliminate the reference to an agency's authority because purpose and need statements have always been informed by the scope of the agency's statutory decision-making authority irrespective of whether the action is an application for authorization. A reference to an agency's statutory authority in this one context therefore seems unnecessary.

To promote informed decision making, transparency, and public engagement, a properly drawn purpose and need statement should lead to consideration of the reasonable alternatives to the proposed action, consistent with NEPA's requirements. *See* 42 U.S.C. 4332(2)(C). While a purpose and need statement that is too narrow is inconsistent with NEPA's requirement to consider alternatives to the proposed action, so too is a boundless analysis of alternatives. Rather, agencies are guided by a rule of reason in identifying the reasonable alternatives that are technically and economically feasible and meet the purpose and need of a proposed action. *See, e.g., HonoluluTraffic.com v. Fed. Transit Admin.*, 742 F.3d 1222, 1230 (9th Cir. 2014).

For example, a private applicant seeking a right-of-way on Federal land may want to site the right-of-way at a specific location and may, correspondingly, frame the applicant's goals as a right-of-way with a particular location or route. However, the agency with jurisdiction over the proposed action may want to consider a range of reasonable locations for the right-of-way that would, for example, avoid environmental impacts or reduce conflicts with other programs or plans.

Inherent in the NEPA process is the consideration of the public interest when developing a purpose and need statement, including analyzing proposed actions and alternatives. As the U.S. Court of Appeals for the Seventh Circuit explained in *Simmons v. U.S. Army Corps of Engineers*, it is contrary to NEPA for agencies to "contrive a purpose so slender as to define competing 'reasonable alternatives' out of consideration (and even out of existence)." 120 F.3d 664,

666 (7th Cir. 1997) (citing 42 U.S.C. 4332(2)(E)). The court explained that constricting the definition of the project's purpose could exclude truly reasonable alternatives, making an EIS incompatible with NEPA's requirements. *Id.*; see also, e.g., *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1070 (9th Cir. 2010) ("Agencies enjoy 'considerable discretion' to define the purpose and need of a project. However, 'an agency cannot define its objectives in unreasonably narrow terms.'" (internal citations omitted)).

During the rulemaking process for the 2020 NEPA Regulations, numerous public comments addressed the purpose and need provision. Some commenters supported limiting the purpose and need to the goals of the applicant in order to narrow the number of alternatives agencies must consider and shorten the timeframe for the environmental review. Other commenters expressed the view that this provision would result in purpose and need statements and environmental reviews that give undue deference to applicants. Some commenters also stated that the proposed change would unduly elevate the goals of applicants over the needs of the public and Federal agencies' purview to consider the public interest. In reconsidering the approach taken in the 2020 Rule, CEQ reviewed these comments. As discussed in this section, CEQ considers the proposed reversion to the 1978 language on purpose and need to better reflect NEPA's objectives. Upon further consideration, CEQ does not consider that the language added by the 2020 Rule would necessarily lead to more efficient reviews and finds a lack of evidence to support that claim. CEQ requests comment on this proposed change and the potential effects of this change on the environmental review process, including timeframes for environmental review.

CEQ also proposes to make a conforming edit to the definition of "reasonable alternatives. The 2020 Rule defines "reasonable alternatives" to mean "a reasonable range of alternatives that are technically and economically feasible, meet the purpose and need for the proposed action, and, where applicable, meet the goals of the applicant." 40 CFR 1508.1(z) (emphasis added). CEQ's proposed change would be consistent with the proposed change to purpose and need, by deleting the reference in "reasonable alternatives" to the goals of the applicant for the same reasons discussed above regarding the proposed change to the purpose and need section, § 1502.13.

B. Agency NEPA Procedures (§ 1507.3)

CEQ proposes to revise § 1507.3(a) and (b) to clarify that while agency NEPA procedures need to be consistent with the CEQ regulations, agencies have the discretion and flexibility to develop procedures beyond the CEQ regulatory requirements, enabling agencies to address their specific programs and the contexts in which they operate. Specifically, the proposed rule would remove language from § 1507.3(a) stating that where existing agency NEPA procedures are "inconsistent" with the CEQ regulations, the CEQ regulations apply "unless there is a clear and fundamental conflict with the requirements of another statute." The proposed rule also would remove from § 1507.3(b) the language requiring agencies "to eliminate any inconsistencies" with the CEQ regulations and the prohibition on agencies imposing additional procedures or requirements beyond the CEQ regulations unless those additional procedures promote agency efficiency or are required by law. Collectively, these "ceiling provisions" make the CEQ regulations a ceiling for agency NEPA procedures, which departed from CEQ's and Federal agencies' prior understanding and practice that CEQ's NEPA regulations provide a floor for environmental review procedures.

As noted in section II of this preamble, CEQ amended paragraph (b) in June 2021 to provide agencies until September 14, 2023, to propose updates to their agency procedures. This NPRM does not propose to change that date. In proposing these revisions, CEQ is affirming that agencies have the authority and discretion to develop and implement NEPA procedures beyond those specified in the CEQ regulations to address the unique contexts in which they operate, and that CEQ will continue to ensure that such additional procedures are consistent with CEQ's regulations through its consistency review process set forth in 40 CFR 1507.3(b)(2).

Prior to the 2020 NEPA Regulations, Federal agencies could develop NEPA procedures of their own to augment the CEQ regulations, so long as those procedures met or exceeded the degree of environmental review required by the CEQ regulations. CEQ's proposal better meets NEPA's statutory requirements and purpose to provide flexibility to agencies in carrying out their NEPA requirements, including by allowing agencies to adopt agency-specific NEPA procedures that align with their unique missions or circumstances. Agencies should be able to tailor their procedures

to meet their unique statutory mandates and include additional procedures or requirements beyond those outlined in CEQ's NEPA regulations, especially if doing so will promote better decisions, improve environmental or community outcomes, or spur innovation that advances NEPA's policies.

For example, agency procedures could include more specific requirements for the development of environmental assessments to facilitate the decision-making process, such as requiring multiple alternatives or documentation of alternatives considered but dismissed. Procedures also could require public hearings or provide for more specific consideration or evaluation of certain issues such as air and water quality impacts, environmental justice considerations, or habitat effects. For example, the National Oceanic and Atmospheric Administration (NOAA), which among other things, is responsible for the stewardship of the Nation's ocean resources and their habitat, might adopt agency-specific procedures on the analysis of impacts to species or habitats protected by the Endangered Species Act, the Marine Mammal Protection Act, or the Magnuson-Stevens Fishery Conservation and Management Act, as well as other vulnerable marine and coastal ecosystems. CEQ has heard from Federal agencies that the ceiling provisions have created confusion as to whether agencies can continue to carry out their agency-specific procedures or adopt new procedures to implement NEPA for their programs and authorities.

CEQ reviews any proposed changes to agency NEPA procedures before their adoption to ensure the procedures are consistent with NEPA and the CEQ regulations. See 40 CFR 1507.3. That review process provides the opportunity to discuss the reasons behind any new or additional procedures or requirements proposed by agencies. This also allows CEQ to promote consistency across the Federal Government without limiting agencies' flexibility to do more than the CEQ regulations describe or otherwise inhibiting innovation.

Removing these ceiling provisions also improves alignment of the NEPA Regulations with NEPA's statutory text, which directs agencies to pursue the statute's goals "to the fullest extent possible." 42 U.S.C. 4332. The legislative history of NEPA indicates that the intent behind this statement was to ensure that all Federal agencies comply with NEPA as well as their statutory authorities and that "no agency shall utilize an excessively

narrow construction of its existing statutory authorizations to avoid compliance.”²³

Additionally, removing these sentences would allow agencies to fully pursue NEPA’s aims by allowing them to establish procedures specific to their missions and authorities that may provide for additional environmental review and public participation. See 42 U.S.C. 4332. CEQ would continue to perform its longstanding role of reviewing any proposed agency-specific NEPA procedures to ensure that they are consistent with, but not necessarily identical to, CEQ’s regulations. The proposed change would also help Federal agencies ensure that their NEPA procedures, and the NEPA documents and processes that follow those procedures, meet the goal of NEPA to provide for the protection and enhancement of the environment and human health.

Since all agencies are charged with administering NEPA—not only CEQ—agencies should be allowed to pursue the environmental aims of the statute, including by adopting and carrying out procedures that require additional or more specific environmental analysis than called for by the CEQ regulations. NEPA also expressly instructs agencies to develop methods and procedures for the development of EISs, indicating that agencies are intended to take responsibility for their own procedures, even while consulting with CEQ. See 42 U.S.C. 4332(2)(B). Eliminating the 2020 NEPA Regulations’ ceiling provisions would allow agencies to carry out their NEPA obligations to the “fullest extent possible.” See 42 U.S.C. 4332.

The public extensively commented on the ceiling provisions during the rulemaking for the 2020 NEPA Regulations. Many commenters opposed the addition of these provisions, expressing the view that it is important for agencies to have flexibility to meet NEPA’s statutory requirements and establish the procedures and requirements necessary to implement NEPA. Commenters stated that precluding an agency from applying its expertise would arbitrarily limit the role of agencies responsible for implementing NEPA. Some commenters found that the 2020 NEPA Regulations did not adequately justify the addition of these provisions or clearly articulate what problem the change was trying to solve. A few commenters also noted that the proposed changes could interfere with state and Federal collaboration or coordination to the extent they would prevent Federal agencies from adopting

NEPA procedures that integrate with state review processes that have more stringent requirements and procedures than those set out in the proposed rule. The commenters noted that impairing Federal agencies’ coordination with states would create greater complexity and uncertainty for applicants and potentially additional delays and paperwork. The few comments in support of the change expressed general support or stated that including ceiling provisions would reduce costs and delays—a rationale that appears in the NPRM for the 2020 Rule—but did not provide an explanation or basis for that statement.

In developing this proposal, CEQ considered these comments as well as the rationale provided for the 2020 Rule and, in alignment with the discussion provided earlier in this section, disagrees with the rationale provided for the 2020 Rule and agrees with the comments that opposed the addition of the ceiling provisions. Even if the ceiling provisions would reduce costs and delays in some circumstances, which commenters did not provide evidence to support, CEQ considers the benefits of agency flexibility to outweigh the potential costs and delays. NEPA is more than a check-the-box paperwork exercise. Providing agencies flexibility to integrate their NEPA reviews into their unique programs can both make the decision-making process more efficient—because the process can be tailored to the particularities of agency programs—and more effective because a more tailored environmental review process may result in environmental reviews that better inform the decision maker and the public. Moreover, CEQ retains authority to review proposed agency procedures for consistency with CEQ’s regulations and can evaluate specific proposals made by agencies at that time and work with the agencies to ensure implementing procedures do not result in undue cost or delay. CEQ invites public comment on this proposed provision.

C. Definition of “Effects” or “Impacts” (§ 1508.1(g))

NEPA requires Federal agencies to examine the environmental effects of their proposed actions and alternatives and any adverse environmental effects that cannot be avoided if the proposed action is implemented. 42 U.S.C. 4332(2)(C). CEQ proposes to revise the definition of “effects” or “impacts” in § 1508.1(g) to restore the substance of the definitions of “effects” and “cumulative impacts” contained in the 1978 NEPA Regulations with some

minor, non-substantive changes for consistency with the current format of the Code of Federal Regulations. Specifically, CEQ proposes to restore the definitions of “direct” and “indirect” effects, and “cumulative impacts” from the 1978 NEPA Regulations, 40 CFR 1508.7 and 1508.8 (2019), by incorporating them into the definition of “effects” or “impacts,” such that each reference to these terms throughout 40 CFR parts 1500 through 1508 would include direct, indirect, and cumulative effects.

Direct effects are effects caused by the action and occur at the same time and place. 40 CFR 1508.8(a) (2019). Indirect effects are effects caused by the action that are later in time or farther removed in distance but are still reasonably foreseeable. *Id.* at § 1508.8(b). Cumulative effects are effects resulting from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of who undertakes the other actions. *Id.* at § 1508.7.

CEQ’s proposal would remove the language from paragraph (g) defining “effects” as those “that are reasonably foreseeable and have a reasonably close causal relationship.” The proposal also would remove and replace paragraph (g)(2), which states that a “but for” causal relationship is insufficient to make an agency responsible for a particular effect under NEPA; generally excludes effects that are remote in time, geographically remote, or the product of a lengthy causal chain; and fully excludes effects that the agency has no ability to prevent due to its limited statutory authority or would occur regardless of the proposed action. The proposed rule also would remove and replace paragraph (g)(3), which states that an agency’s analysis of effects must be consistent with the definition of “effects” and explicitly repeals the definition of cumulative impact in 40 CFR 1508.7 (2019). CEQ proposes to remove this language because it creates confusion and could be read to improperly narrow the scope of environmental effects relevant to NEPA analysis, contrary to NEPA’s purpose.

CEQ’s proposal would retain the introductory phrase added in the 2020 Rule that defines “effects” as “changes to the human environment from the proposed action or alternatives.” This revision eliminated the circular definition (“effects” include effects) of the 1978 NEPA Regulations. Finally, CEQ does not propose to include the statement from the 1978 NEPA Regulations that “effects” and “impacts” as used in the regulations are

²³ H. Rep. No. 91–765, at 9–10 (1969).

synonymous, as this statement would be redundant as the definition defines both “effects” and “impacts” together.

1. Reinstating “Direct” and “Indirect” Effects

CEQ proposes to restore the terms “direct” and “indirect” to the definition of “effects” to realign the regulations with longstanding agency practice²⁴ and judicial decisions interpreting NEPA. Based on CEQ’s extensive experience implementing NEPA, this change would better reflect NEPA’s statutory purpose and intent and be more consistent with case law, as courts have interpreted the NEPA statute to require agencies to analyze the reasonably foreseeable direct and indirect effects of a proposed action and alternatives. *See, e.g., Minn. Pub. Int. Rsch. Grp. v. Butz*, 498 F.2d 1314, 1322 (8th Cir. 1974) (stating that NEPA “is concerned with indirect effects as well as direct effects,” and emphasizing long-term effects as a reason that a logging project would significantly affect the environment and require an EIS); *see also, e.g., Sierra Club v. Fed. Energy Reg. Comm’n*, 867 F.3d 1357, 1371–72 (D.C. Cir. 2017); *San Juan Citizens All. v. U.S. Bureau of Land Mgmt.*, 326 F. Supp. 3d 1227, 1244 (D.N.M. 2018) (holding that greenhouse gas emissions are foreseeable indirect effects of leases for fossil fuel production and approvals of pipelines that transport fossil fuels). As reflected in many of the public comments to the 2020 Rule as well as in CEQ’s discussions with agency NEPA practitioners who have asked CEQ for clarification since the 2020 Rule went into effect, this change would eliminate confusion caused by the modified definition and ensure that the NEPA process fully and fairly considers the appropriate universe of effects, such as air and water pollution, greenhouse gas emissions that contribute to climate change, and effects on communities with environmental justice concerns.

While the 2020 NEPA Regulations retained the definition of “direct” effects without using the term, the revised definition creates ambiguity regarding whether and to what extent indirect effects are included in the definition of “effects.” In particular, the definition states in paragraph (g) that effects “may include effects that are later in time or farther removed in distance” but then states in paragraph (g)(2) that effects should generally not

be considered if they are remote in time or geographically remote. CEQ’s proposed changes would provide clarity to agencies, practitioners, and the public by restoring the terms and definitions of “direct” and “indirect,” as these terms can help agencies and the public evaluate and understand the full scope of reasonably foreseeable effects in NEPA reviews.

This reinstatement also would ensure that agencies consider the full range of reasonably foreseeable effects in the NEPA process, consistent with NEPA’s goal of facilitating reason-based decision making that protects public health and the environment, as well as this Administration’s policies to be guided by science and to address environmental protection, climate change, and environmental justice. For example, air pollution, including greenhouse gas emissions, released by fossil fuel combustion is often a reasonably foreseeable indirect effect of proposed fossil fuel extraction that agencies should evaluate in the NEPA process, even if the pollution is remote in time or geographically remote from a proposed action. And even where an agency does not exercise regulatory authority over all aspects of a project, it may be appropriate to consider and compare the air pollution and greenhouse gas emission effects that the proposal and the reasonable alternatives would have on the environment, even if the agency does not have control over all of the emissions that the alternatives would produce. The consideration of such effects can provide important information on the selection of a preferred alternative; for example, an agency decision maker might select the no action alternative, as opposed to a fossil fuel leasing alternative, on the basis that it best aligns with the agency’s statutory authorities and policies with respect to greenhouse gas emission mitigation.²⁵

²⁵ Agencies may consider all available tools and resources in assessing GHG emissions and climate change effects of their proposed actions, including, as appropriate and relevant, CEQ’s 2016 “Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews,” 81 FR 51866 (Aug. 5, 2016). Additionally, under E.O. 13990, the Interagency Working Group (IWG) on the Social Cost of Greenhouse Gases published interim estimates and is preparing updated estimates, which agencies may find helpful in considering greenhouse gas emission effects and mitigation as part of the NEPA process. *See* https://www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf?source=email. This proposed rule does not specifically address the IWG’s interim or final Social Cost of Greenhouse Gases estimates. More information on the interim estimates is available from the Office of Information

Use of the terms “direct” and “indirect” also can help explain both adverse and beneficial effects over various timeframes. For instance, a utility-scale solar facility could have short-term direct adverse effects, such as land impacts associated with construction. The facility also could have long-term indirect beneficial effects, such as reductions in air pollution, including greenhouse gas emissions, from the renewable energy generated by the solar facility that displaces more greenhouse gas-intensive energy sources (such as coal or natural gas) as an electricity source for years or decades into the future. Consistent with CEQ’s proposed restored definition, such indirect effects could be caused by the action to authorize a new solar facility, and would be later in time or farther removed in distance yet still reasonably foreseeable. Fully evaluating the effects of the facility would require identifying and evaluating both the direct and indirect effects of the proposed action.

The 2020 NEPA Regulations also removed the explanatory examples of indirect effects, including growth-inducing effects and other effects related to induced changes in the pattern of land use, population density, or growth rate, and related effects on air and water and other natural systems, including ecosystems. Restoring these examples is appropriate to highlight indirect effects that may be associated with myriad proposed Federal actions, such as expanding or repairing Federal highways or authorizing new renewable energy projects.

Numerous public comments discussed the elimination of references to “direct” and “indirect” in the definition of “effects” during the rulemaking for the 2020 NEPA Regulations. Commenters who supported the elimination of “direct” and “indirect” expressed views that the existing language creates confusion, that removal of the terms could help reduce the length of NEPA documents, and that retaining the terms would lead to an increase in litigation. Commenters also raised concerns that the terms have expanded the scope of NEPA analysis without serving NEPA’s purpose of informed decision making but did not provide bases, analyses, or evidence to support these conclusions. The 2020 Rule adopted the position of these comments. CEQ considers the disclosure of both direct and indirect effects to be critical to the informed

and Regulatory Affairs. *See* <https://www.whitehouse.gov/wp-content/uploads/2021/06/Social-Cost-of-Greenhouse-Gas-Emissions.pdf>.

²⁴ *See, e.g.,* Bureau of Land Management National Environmental Policy Act Handbook H–1790–1, sec. 6.8.2 (January 2008); 36 CFR 220.4(f), 220.7(b)(iv) (Forest Service); 32 CFR 651.29(b), 651.34(f), 651.51(a)(3), Appendix to E to Part 651—Content of EIS (Army Corps of Engineers).

decision-making process such that the benefits of any such disclosure outweigh any potential for shorter NEPA documents or timeframes. Moreover, a well-drafted NEPA document can both be concise and supported by thorough analysis, and agencies have decades of experience considering the direct and indirect effects of their proposed actions. CEQ considers the potential for reduced litigation from the 2020 changes to be speculative, especially given the confusion that has resulted from deleting these familiar terms. Finally, CEQ expects that restoring these definitions that have been in place and in use for decades will better clarify the effects agencies need to consider in their NEPA analyses and may even help avoid delays in NEPA reviews.

The vast majority of comments on the 2020 NEPA Regulations opposed the removal of the terms, and CEQ views those comments as supporting its proposal to restore the terms “direct” and “indirect” to the definition of “effects.” Commenters expressed views that retaining the terms would reduce confusion and litigation. They also expressed views that direct and indirect effects are critical elements of the evaluation of potential environmental effects of a proposed action, and they raised concerns that by deleting the term “indirect,” agencies may not adequately consider long-term or geographically remote impacts, including greenhouse gas emissions or water pollution that travels downstream. Commenters supported their views by pointing to CEQ’s longstanding guidance and decades of agency guidance and court decisions using the terms to address effects pursuant to NEPA. Many commenters argued that removal of these terms would be contrary to the intent of the statute, and that consideration of both direct and indirect effects is essential to determining significance. CEQ invites comment on these proposed changes.

2. Adding “Cumulative Effects” to the Definition of “Effects”

CEQ proposes to revise § 1508.1(g)(3) by restoring, with minor modifications, the definition of “cumulative impacts” from the 1978 NEPA Regulations and striking the current provision that repealed that definition. Analysis of reasonably foreseeable cumulative effects is integral to sound and complete environmental review. Cumulative effects analysis is an essential component of NEPA analysis, as it allows agencies and the public to understand how the incremental impacts of a proposed action contribute

to cumulative environmental problems such as air pollution, water pollution, climate change, and biodiversity loss, among others. Today, science and data confirm that cumulative environmental harms, including repeated or frequent exposure to toxic air or water pollution, threaten human and environmental health and poses undue burdens on historically marginalized communities.²⁶ CEQ seeks to ensure that agencies fully analyze reasonably foreseeable cumulative effects before Federal decisions are made by restoring the term and its definition.

The 2020 Rule’s deletion of the definition of “cumulative impacts” did not exclude reasonably foreseeable effects from consideration merely because they could be categorized as cumulative effects. In responding to comments about potential effects on threatened and endangered species, the preamble to the 2020 Rule explains that “the final rule does not ignore cumulative effects on listed species.”²⁷ CEQ similarly explained in the Final Rule Response to Comments that the 2020 Rule did not automatically exclude from analysis effects falling within the deleted definition of “cumulative impacts.”²⁸ However, CEQ considers the deletion of the longstanding term to have the potential to create confusion about when and if agencies should analyze cumulative effects, and creates uncertainty regarding this type of effects analysis contrary to longstanding agency practice and NEPA’s purpose. For example, CEQ has heard from Federal agency NEPA practitioners both individually and in agency meetings that they would like clarification about how to address cumulative effects, including whether it remains permissible to use the term, in light of the changes made in 2020. In addition, outside stakeholders have raised concerns in meetings and listening sessions regarding the deletion of the term in light of the potential impact this could have in truncating the environmental review and disclosure of important categories of effects. Additionally, public comments received

on the proposed 2020 Rule raised such concerns. By restoring the definition of cumulative effects, the proposed rule would clarify that agencies must analyze and disclose reasonably foreseeable cumulative effects.

Since its initial NEPA guidelines in 1970, CEQ has interpreted the statute as requiring consideration of cumulative effects. In its 1970 interim guidelines, CEQ provided that agencies should construe the statutory clause “major Federal actions significantly affecting the quality of the human environment” “with a view to the overall, *cumulative* impact of the action proposed (and of further actions contemplated).”²⁹ CEQ explained that agencies should consider “that the effect of many Federal decisions about a project or complex of projects can be individually limited but cumulatively considerable” because, for instance, agencies may provide funds over a period of years or multiple agencies may individually make decisions about partial aspects of a project.³⁰ The guidelines further stated that an agency should prepare an EIS “if it is reasonable to anticipate a cumulatively significant impact on the environment from the Federal action.”³¹

These initial guidelines also interpreted the requirement in section 102(2)(C)(iv) to mean that “[t]he relationship between local short-term uses of man’s environment and the maintenance and enhancement of long-term productivity . . . requires the agency to assess the action for *cumulative and long-term effects* from the perspective that each generation is trustee of the environment for succeeding generations.”³² This interpretation is reflected in the 1971 final guidelines³³ and the 1978 NEPA Regulations.³⁴ Decades of agency practice and CEQ guidance affirm the interpretation that NEPA requires analysis of cumulative effects.³⁵ For example, in 1997 CEQ noted that cumulative effects analysis is “critical” for the purposes of evaluating project

²⁹ 35 FR 7390, 7391 (May 12, 1970) (emphasis added).

³⁰ *Id.*

³¹ *Id.*

³² *Id.* at 7392 (emphasis added).

³³ 36 FR 7724 (Apr. 23, 1971).

³⁴ See 43 FR 55978 (Nov. 23, 1978).

³⁵ See, e.g., CEQ, Considering Cumulative Effects Under the National Environmental Policy Act (1997), https://ceq.doe.gov/publications/cumulative_effects.html; U.S. EPA, EPA 315-R-00-002, Consideration of Cumulative Impacts in EPA Review of NEPA Documents 1 (1999) (“Because federal projects cause or are affected by cumulative impacts, this type of impact must be assessed in documents prepared under NEPA.”).

²⁶ See, e.g., Mercedes A. Bravo et al., *Racial Isolation and Exposure to Airborne Particulate Matter and Ozone in Understudied U.S. Populations: Environmental Justice Applications of Downscaled Numerical Model Output*, 92–93 *Env’t Int’l* 247 (2016) (finding that long-term exposure to particulate matter is associated with racial segregation, with more highly segregated areas suffering higher levels of exposure).

²⁷ 85 FR 43355 (July 16, 2020).

²⁸ Council on Environmental Quality, Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act Final Rule Response to Comments 467 (June 30, 2020), <https://www.regulations.gov/document/CEQ-2019-0003-720629>.

alternatives and developing appropriate mitigation strategies.³⁶

CEQ's proposal to reinstate the definition of "cumulative impacts" aligns with longstanding legal precedent interpreting NEPA to require agencies to consider cumulative effects. Even before CEQ issued regulations on cumulative effects, the U.S. Supreme Court had interpreted NEPA to include them. In 1976, the Court held that NEPA requires consideration of cumulative effects "when several proposals . . . that will have *cumulative* or synergistic environmental impact upon a region are pending concurrently before an agency, their environmental consequences must be considered together." *Kleppe v. Sierra Club*, 427 U.S. 390, 410 (1976) (emphasis added).

Numerous commenters on the proposed 2020 Rule raised concerns that the 2020 Rule could be interpreted to eliminate consideration of cumulative effects and eliminating consideration of cumulative effects would undermine NEPA's purpose and environmental protection goals, and could interfere with the necessary analysis of a proposed action's impacts. Other commenters expressed views that indirect and cumulative effects often disproportionately affect Tribes, minority, and low-income populations, and excluding the details of such effects from NEPA analyses could lead agency decision makers to unknowingly make decisions that negatively impact Tribes or communities with environmental justice concerns. Some commenters who favored striking the requirement to analyze cumulative effects expressed views that the consideration of cumulative impacts could be redundant and that removal of cumulative effects would reduce the time it takes to complete the NEPA process. Other commenters were neutral on the change but expressed views that the proposed change would be controversial and could lead to potential litigation or delays. The 2020 Rule eliminated the "cumulative effects" language, adopting the view that the analysis of cumulative effects was too broad, categorizing and determining the scope of cumulative effects is difficult and can divert agency resources from the most significant effects, and the analysis of cumulative effects could require agency attention to information that is irrelevant or inconsequential, and did not lead to informed decision making.

CEQ considered these comments and the rationale described in the 2020 Rule when developing this proposal. CEQ has changed its view and does not consider

the term cumulative effects to be too broadly defined in the 1978 NEPA Regulations or too difficult for agencies to meaningfully implement. As explained earlier in this section, CEQ's own prior guidelines and guidance, along with decades of agency practice and longstanding legal precedent have interpreted NEPA to require agencies to consider cumulative effects. While the 2020 Rule found that cumulative effects was previously too broadly defined, the removal of "cumulative effects" created an even less clear definition of effects, resulting in more confusion and uncertainty about what type of effects analysis is necessary. Rather than diverting agency resources or focusing on effects that are irrelevant or inconsequential, as the 2020 Rule stated with respect to cumulative effects analysis, CEQ considers analysis of reasonably foreseeable cumulative effects to be an important part of NEPA analysis, helping the public and decision makers understand the full scope of potential impacts from a proposed action. Reasonably foreseeable cumulative effects are not irrelevant or inconsequential; for example, aggregate air and water pollution and habitat impacts affect long-term environmental conditions, wildlife, and communities—including in regions already overburdened by pollution. Analyzing reasonably foreseeable cumulative effects is consistent with NEPA's text and purpose and better informs decision makers about important aspects of proposed actions and their alternatives. Further, CEQ is not aware of any evidence supporting the claim that evaluation of cumulative effects necessarily leads to longer timelines, especially given the long history of agency and practitioner experience with this type of analysis as well as modern techniques that leverage science and technology to make reviews comprehensive yet efficient. And clarity on analyzing reasonably foreseeable cumulative effects, as proposed, would outweigh the speculative potential for shorter NEPA documents or timeframes.

CEQ shares the view that environmental reviews should be efficient and effective and will continue to evaluate the NEPA process for opportunities to improve timeliness consistent with NEPA's purposes. However, CEQ disagrees that requiring analysis of reasonably foreseeable cumulative effects causes unacceptably long NEPA processes. Further, by deleting the definition of cumulative effects, the 2020 Rule did not prohibit agencies from evaluating reasonably foreseeable cumulative effects and

therefore, it was not certain to result in faster and less burdensome NEPA analyses. Rather, in affirmatively repealing the defined term from the regulations, the 2020 Rule has caused confusion and cast doubt as to whether agencies can and should continue to do this analysis. Finally, consideration of cumulative effects is important in order to fully inform agency decision makers before actions are taken, and effects analysis remains bound by the notion of reasonable foreseeability. CEQ invites comment on this proposed change.

3. Removing Limitations on Effects Analysis

In proposing to restore the definition of "effects" from the 1978 NEPA Regulations, CEQ would remove changes made in the 2020 Rule stating that effects are those "that are reasonably foreseeable and have a reasonably close causal relationship to the proposed action or alternatives." 40 CFR 1508.1(g). CEQ also proposes to remove and replace § 1508.1(g)(2), which states that "a 'but for' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA;" agencies generally should not consider effects that are remote in time, geographically remote, or the product of a lengthy causal chain; and agencies should not consider effects that the agency has no ability to prevent due to its limited statutory authority. Finally, the proposed rule would remove as superfluous and replace § 1508.1(g)(3), which states that "[a]n agency's analysis of effects shall be consistent with this paragraph." This phrase seeks to enforce the limitations added to the "effects" definition in the 2020 Rule, which would be unnecessary if the limitations are removed.

The definition of "effects" in the 1978 NEPA Regulations gave agencies the discretion to identify the reasonably foreseeable effects of a proposed action and its alternatives in light of NEPA's goals. It is CEQ's view that this approach provides for more sound decision making, including decisions informed by science, and a more knowledgeable and engaged public than the definition of "effects" in the 2020 NEPA Regulations. Whether an effect is reasonably foreseeable is a context-specific inquiry that Federal agencies have engaged in for more than 40 years. Agencies have made these determinations guided by agency procedures and practice, evolving scientific understanding about natural systems and environmental outcomes, and court decisions.

The current definition of "effects" has internal inconsistencies, which make it

³⁶ CEQ, *supra* note 35, at v.

confusing to apply. The introductory paragraph of 40 CFR 1508.1(g) states that effects “may include” those that are later in time and farther removed in distance, but paragraph (g)(2) states that effects “should generally not be considered if they are remote in time, geographically remote, or the product of a lengthy causal chain.” This creates confusion as to whether agencies can or should consider these types of effects, potentially leading to inconsistent application of NEPA, public confusion or controversy, and enhanced risk of litigation and concomitant delays in the NEPA process.

Removing the language from § 1508.1(g)(2) limiting the consideration of temporally or geographically removed environmental effects and effects that are a product of a lengthy causal chain would better align with the statutory text, which does not include any of these qualifiers and instead directs agencies to produce a detailed statement on the “environmental impact of [a] proposed action,” “any adverse environmental effects which cannot be avoided,” and “the relationship between local short-term uses of man’s environment and the maintenance and enhancement of long-term productivity.” 42 U.S.C. 4332(2)(C) (emphasis added). Many consequential reasonably foreseeable environmental effects, such as toxic releases into air or water and greenhouse gas emissions that contribute to climate change, often occur remote in time or place from the original action or are a product of a causal chain. For instance, when considering a potential Federal action that would permit fossil fuel extraction, it is reasonably foreseeable that the fossil fuel will be extracted, transported, and ultimately combusted to create energy, all of which cause air pollution that can have adverse public health and environmental effects. Thus, the 2020 Rule’s limiting language could cause Federal agencies to omit critical categories of effects from analysis and disclosure, frustrating NEPA’s core purpose and Congressional intent. Similarly, the statement that “a ‘but for’ causal relationship is insufficient to make an agency responsible for a particular effect under NEPA” added a confusing new standard to apply that could cause agencies to omit reasonably foreseeable effects in NEPA reviews, contrary to NEPA’s statutory purpose to promote informed decision making. CEQ disagrees that this language would help agencies better understand what effects they need to analyze and discuss, helping to reduce delays and paperwork with unnecessary analyses. Rather, the

new language poses new implementation and interpretation challenges that could, in turn, create delays and conflict. The definition of “effects” that CEQ proposes to restore does not require that agencies disclose every possible effect; rather, the standard under NEPA has long been whether effects are reasonably foreseeable.

Similarly, the direction in the 2020 Rule to exclude “effects that the agency has no ability to prevent due to its limited statutory authority or would occur regardless of the proposed action” unduly limits agency discretion. CEQ proposes to remove this limitation because agencies may conclude that analyzing and disclosing such effects will provide important information to decision makers and the public. For example, agencies may need to analyze and disclose reasonably foreseeable growth and development that will occur if they authorize infrastructure projects such as highway interchanges or causeways, even if they do not have general land use authority. *See, e.g., Sierra Club v. Marsh*, 769 F.2d 868 (1st Cir. 1985); *City of Davis v. Coleman*, 521 F.2d 661 (9th Cir. 1975). Reasonably foreseeable environmental effects do not fall neatly within discrete agency jurisdictional or regulatory confines; rather, agencies make decisions about reviews and authorizations that have real world impacts, including effects like water or air pollution that are measurable and ascertainable yet may have physical effects outside an agency’s statutory purview.

CEQ’s proposal to restore the definition of “effects” from the 1978 NEPA Regulations is consistent with the U.S. Supreme Court’s decision in *Department of Transportation v. Public Citizen*, 541 U.S. 752 (2004), which the 2020 Rule identified as the authority for the revised definition. In this case, the Supreme Court explained that NEPA and the 1978 NEPA Regulations are governed by a “rule of reason.” *Id.* at 767. The Federal Motor Carrier Safety Administration (FMCSA) was required to issue certification and safety regulations for Mexican trucks entering the United States, *id.* at 760, and had no ability to deny certification if trucks met the requirements, *id.* at 758–59. The Court held that, based on FMCSA’s limited statutory authority, it was not arbitrary and capricious for FMCSA to exclude from its NEPA analysis the effects of trucks entering the United States that would result from the President’s commitment to lift a moratorium on Mexican truck entry once FMCSA issued the regulations. *See id.* at 770. By affirming FMCSA’s

implementation of the 1978 NEPA Regulations under a substantial deference standard of review, the Court did not hold that agencies *may not* consider a broader range of effects in other circumstances, as the 2020 Rule suggests. Instead, the Court held that FMCSA’s effects analysis in the specific factual and legal context of its proposed action was reasonable and not arbitrary and capricious.

It is CEQ’s view that establishing a regulatory limitation on the scope of NEPA analysis drawn from *Public Citizen* does not lead to improved agency decision making, enhanced public participation, or a better-informed public. Rather, as CEQ has heard from NEPA practitioners and outside stakeholders, these limitations undermine sound decision making by creating confusion with respect to NEPA implementation, departing from CEQ’s consistent interpretation of NEPA prior to 2020, breaking from science-based decisions, and potentially limiting relevant NEPA analysis with negative repercussions in critical areas such as climate change and environmental justice. NEPA has long been understood to require only analysis of effects that are “reasonably foreseeable,” but the limitations added by the 2020 NEPA Regulations could undermine longstanding agency discretion to determine the appropriate scope of analysis or result in agencies making less informed decisions contrary to NEPA’s stated goals.

Numerous commenters addressed these limitations during the rulemaking for the 2020 NEPA Regulations. Many opposed the limitations, expressing views that requiring a close causal relationship could be confusing to implement and could inappropriately constrain consideration of reasonably foreseeable impacts of a proposed action on the human environment, undermining the purpose of NEPA. Those opposed also expressed views that the new limitations could be used to justify the exclusion of effects of a proposed action including air or water pollution affecting communities or wildlife located outside the immediate vicinity of the proposed action that are nonetheless reasonably foreseeable. For example, the limitations could cause agencies to exclude consideration of the effects to a community that relies on a water source downstream from a project area that is indirectly impacted by the proposed action’s water quality effects. Some commenters also stated that the term “remote” is too vague and relative. Those who supported the limitations expressed views that the changes were in keeping with the judicial precedent

cited in the proposed rule and could help cut the length and time of NEPA analysis by reducing burdens on Federal agencies; however, commenters did not provide evidence demonstrating how inclusion of these limitations would help cut the length and time of NEPA analysis.

Upon reconsidering the position taken in the 2020 NEPA Regulations, CEQ proposes to remove these provisions in order to improve clarity on the types of effects that agencies must consider, eliminate restrictions that may conflict with scientific understanding of environmental outcomes, and better inform decision makers and the public about the full suite of reasonably foreseeable effects of a proposed action and its alternatives. CEQ disagrees that the provisions added in 2020 will reduce burdens on Federal agencies, given that Federal agencies have long operated under the definition of “effects” as defined in the 1978 NEPA Regulations and may have existing NEPA procedures aligned with the 1978 definitions. The 2020 Rule indicated that the added provisions would help agencies better understand what effects need to be analyzed and discussed and would reduce delays and unnecessary analysis. However, agencies have indicated confusion about how to apply the “close causation” and “but for” limitations in the current definition of effects and are concerned that the 2020 Rule may preclude them from considering the same range of effects as the 1978 Regulations. With the proposed changes in this rulemaking, CEQ seeks to reduce confusion and provide clarity on the effects that agencies must consider and does not agree that removing this language will directly result in delays. Additionally, providing clarity to agencies and the public on what is required provides benefits to the environmental review process that outweigh any uncertain potential for shorter timeframes. CEQ requests comment on these changes. CEQ also invites comments on whether CEQ should provide in a Phase 2 rulemaking more specificity about the manner in which agencies should analyze certain categories of effects.

IV. Rulemaking Analyses and Notices

A. Executive Order 12866, Regulatory Planning and Review

E.O. 12866 provides that the Office of Information and Regulatory Affairs will review all significant rules.³⁷ E.O. 13563 reaffirms the principles of E.O. 12866, calling for improvements in the Federal

Government’s regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory objectives.³⁸ This proposed rule is a significant regulatory action that CEQ submitted to OMB for review. The proposed changes would remove uncertainty created by the 2020 Rule to benefit agencies and the public. Removing constraints on agency NEPA analyses could result in longer review timeframes, but these changes do not obligate agencies to undertake longer, more complicated analyses. If agencies choose to consider additional alternatives and conduct more robust analyses, these analyses should improve societal outcomes by improving agency decision making. Since individual cases will vary, the magnitude of potential costs and benefits resulting from these proposed changes are difficult to anticipate. Therefore, CEQ has not quantified them. CEQ invites public comment on those expected impacts and the role they should play in informing the final rule.

B. Regulatory Flexibility Act and Executive Order 13272, Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act (RFA), as amended, 5 U.S.C. 601 *et seq.*, and E.O. 13272³⁹ require agencies to assess the impacts of proposed and final rules on small entities. Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. An agency must prepare an Initial Regulatory Flexibility Analysis (IRFA) unless it determines and certifies that a proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). The proposed rule would not directly regulate small entities. Rather, the proposed rule would apply to Federal agencies and set forth the process for their compliance with NEPA. Accordingly, CEQ hereby certifies that the proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities.

C. National Environmental Policy Act

Under the CEQ regulations, major Federal actions may include regulations. When CEQ issued regulations in 1978, it prepared a “special environmental assessment” for illustrative purposes pursuant to E.O. 11991.⁴⁰ The NPRM for

the 1978 rule stated “the impacts of procedural regulations of this kind are not susceptible to detailed analysis beyond that set out in the assessment.”⁴¹ Similarly, in 1986, while CEQ stated in the final rule that there were “substantial legal questions as to whether entities within the Executive Office of the President are required to prepare environmental assessments,” it also prepared a special environmental assessment.⁴² The special environmental assessment issued in 1986 made a finding of no significant impact, and there was no finding made for the assessment of the 1978 final rule.

CEQ continues to take the position that a NEPA analysis is not required for establishing or updating NEPA procedures. See *Heartwood v. U.S. Forest Serv.*, 230 F.3d 947, 954–55 (7th Cir. 2000) (finding that neither NEPA or the CEQ regulations required the Forest Service to conduct an environmental assessment or an EIS prior to the promulgation of its procedures creating a categorical exclusion). Nevertheless, based on past practice, CEQ has developed a special environmental assessment and has posted it in the docket. CEQ invites comments on the special environmental assessment.

D. Executive Order 13132, Federalism

E.O. 13132 requires agencies to develop an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.⁴³ Policies that have federalism implications include regulations that have substantial direct effects on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the various levels of government. CEQ does not anticipate that this proposed rule has federalism implications because it applies to Federal agencies, not states.

E. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

E.O. 13175 requires agencies to have a process to ensure meaningful and timely input by Tribal officials in the development of policies that have Tribal implications.⁴⁴ Such policies include regulations that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal

⁴¹ *Id.*

⁴² 51 FR 15618, 15619 (Apr. 25, 1986).

⁴³ 64 FR 43255 (Aug. 10, 1999).

⁴⁴ 65 FR 67249 (Nov. 9, 2000).

³⁸ 76 FR 3821 (Jan. 21, 2011).

³⁹ 67 FR 53461 (Aug. 16, 2002).

⁴⁰ 43 FR 25230 (June 9, 1978).

³⁷ 58 FR 51735 (Oct. 4, 1993).

Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. CEQ has assessed the impact of this proposed rule on Indian Tribal governments and has determined preliminarily that the proposed rule would not significantly or uniquely affect these communities but seeks comment on this preliminary determination. However, CEQ plans to engage in government-to-government consultation with federally recognized Tribes and Alaska Native Corporations on its NEPA regulations generally.

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

E.O. 12898 requires agencies to make achieving environmental justice part of their missions by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations.⁴⁵ CEQ has analyzed this proposed rule and preliminarily determined that it would not cause disproportionately high and adverse human health or environmental effects on minority populations and low-income populations. This rule would set forth implementing regulations for NEPA; it is in the agency implementation of NEPA when conducting reviews of proposed agency actions where consideration of environmental justice effects typically occurs. CEQ invites comment on this preliminary determination.

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

Agencies must prepare a Statement of Energy Effects for significant energy actions under E.O. 13211.⁴⁶ CEQ has preliminarily determined that this rulemaking is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

H. Executive Order 12988, Civil Justice Reform

Under section 3(a) of E.O. 12988,⁴⁷ agencies must review their proposed regulations to eliminate drafting errors and ambiguities, draft them to minimize litigation, and provide a clear legal standard for affected conduct. Section

3(b) provides a list of specific issues for review to conduct the reviews required by section 3(a). CEQ has conducted this review and determined that this proposed rule complies with the requirements of E.O. 12988.

I. Unfunded Mandate Reform Act

Section 201 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531, requires Federal agencies to assess the effects of their regulatory actions on state, local, and Tribal governments, and the private sector to the extent that such regulations incorporate requirements specifically set forth in law. Before promulgating a rule that may result in the expenditure by a state, Tribal, or local government, in the aggregate, or by the private sector of \$100 million, adjusted annually for inflation, in any 1 year, an agency must prepare a written statement that assesses the effects on state, Tribal, and local governments and the private sector. 2 U.S.C. 1532. This proposed rule would apply to Federal agencies and would not result in expenditures of \$100 million or more for state, local, and Tribal governments, in the aggregate, or the private sector in any 1 year. This proposed action also would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of 2 U.S.C. 1531–1538.

J. Paperwork Reduction Act

This proposed rule would not impose any new information collection burden that would require additional review or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Parts 1502, 1507, and 1508

Administrative practice and procedure, Environmental impact statements, Environmental protection, Natural resources.

Brenda Mallory,
Chair.

For the reasons discussed in the preamble, the Council on Environmental Quality proposes to amend parts 1502, 1507, and 1508 in title 40 of the Code of Federal Regulations as follows:

PART 1502—ENVIRONMENTAL IMPACT STATEMENT

■ 1. Revise the authority citation for part 1502 to read as follows:

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p.

902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

■ 2. Revise § 1502.13 to read as follows:

§ 1502.13 Purpose and need.

The statement shall briefly specify the underlying purpose and need to which the agency is responding in proposing the alternatives including the proposed action.

PART 1507—AGENCY COMPLIANCE

■ 3. Revise the authority citation for part 1507 to read as follows:

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

■ 4. Amend § 1507.3 by revising paragraphs (a) and the introductory text of paragraph (b) to read as follows:

§ 1507.3 Agency NEPA procedures.

(a) The Council has determined that the categorical exclusions contained in agency NEPA procedures as of September 14, 2020, are consistent with this subchapter.

(b) No more than 36 months after September 14, 2020, or 9 months after the establishment of an agency, whichever comes later, each agency shall develop or revise, as necessary, proposed procedures to implement the regulations in this subchapter. When the agency is a department, it may be efficient for major subunits (with the consent of the department) to adopt their own procedures.

* * * * *

PART 1508—DEFINITIONS

■ 5. Revise the authority citation for part 1508 to read as follows:

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

■ 6. Amend § 1508.1 by revising paragraphs (g) and (z) to read as follows:

§ 1508.1 Definitions.

* * * * *

(g) *Effects* or *impacts* means changes to the human environment from the proposed action or alternatives and include the following:

(1) Direct effects, which are caused by the action and occur at the same time and place.

(2) Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable. Indirect effects may include growth inducing effects and other effects related to induced

⁴⁵ 59 FR 7629 (Feb. 16, 1994).

⁴⁶ 66 FR 28355 (May 22, 2001).

⁴⁷ 61 FR 4729 (Feb. 7, 1996).

changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems.

(3) Cumulative effects, which are effects on the environment that result from the incremental effects of the action when added to the effects of other past, present, and reasonably foreseeable actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative effects can result from individually minor but collectively significant actions taking place over a period of time.

(4) Effects include ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative. Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effects will be beneficial.

* * * * *

(z) *Reasonable alternatives* means a reasonable range of alternatives that are technically and economically feasible, and meet the purpose and need for the proposed action.

* * * * *

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BILLING CODE 3325-F2-P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 19, and 52

[FAR Case 2020-013; Docket No. FAR-2021-0009, Sequence No. 1]

RIN 9000-AO17

Federal Acquisition Regulation: Certification of Women-Owned Small Businesses

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

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement the final rule published by the Small Business Administration

implementing a section of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year (FY) 2015.

DATES: Interested parties should submit comments to the Regulatory Secretariat Division at one of the addresses shown below on or before December 6, 2021 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments in response to FAR Case 2020-013 to the Federal eRulemaking portal at <https://www.regulations.gov> by searching for “FAR Case 2020-013”. Select the link “Comment Now” that corresponds with “FAR Case 2020-013”. Follow the instructions provided on the “Comment Now” screen. Please include your name, company name (if any), and “FAR Case 2020-013” on your attached document. If your comment cannot be submitted using <https://www.regulations.gov>, call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite “FAR Case 2020-013” in all correspondence related to this case. Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check <https://www.regulations.gov>, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Malissa Jones, Procurement Analyst, at 703-605-2815, or by email at Malissa.jones@gsa.gov, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov. Please cite FAR Case 2020-013.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to revise the FAR to implement section 825(a)(1) of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015 (15 U.S.C. 637(m)), Public Law 113-291. Section 825 requires women-owned small business (WOSB) concerns and economically disadvantaged women-owned small business (EDWOSB) concerns to be certified by the Small Business Administration (SBA), a Federal agency, a State government, or a national certifying entity approved by SBA in the WOSB Program to be eligible for set-aside or sole-source awards.

SBA issued a final rule at 85 FR 27650, May 11, 2020, to implement section 825(a)(1). In their final rule, SBA amended 13 CFR part 127 requiring WOSB and EDWOSB concerns be certified by a Federal agency, a State government, the SBA, or a national certifying entity approved by SBA in order to be eligible under the WOSB Program for set-aside or sole-source awards.

II. Discussion and Analysis

The proposed changes to the FAR and the rationale for the proposed changes are summarized in the following paragraphs.

Changes are proposed to FAR 2.101, Definitions, to update the definition of Economically disadvantaged women-owned small business concern (EDWOSB) and Women-owned small business (WOSB) concern eligible under the WOSB Program to add that the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300.

Changes are proposed to FAR 19.308(d), Protesting a firm’s status as an EDWOSB concern or WOSB concern eligible under the WOSB Program, to require a protest to be submitted by email to SBA at wosbprotest@sba.gov. FAR 19.308(d) is also amended to propose deletion of text requiring SBA to consider protests by contracting officers when the apparent successful offeror has failed to provide all of the required documents, as set forth in FAR 19.1503(c). Changes are also proposed to FAR 19.308 to add the requirement that the protest present evidence that the concern is not at least 51 percent owned and controlled by one or more economically disadvantaged women “who are United States citizens”, based on the requirements of 13 CFR part 127. The addition of “United States citizens” aligns the FAR text with SBA’s regulations.

FAR 19.1501, Definition, is reserved to delete the definition of WOSB Program Repository since the WOSB Program Repository is no longer the source for WOSB program eligibility as of October 15, 2020.

FAR 19.1503, Status, is amended to add the requirement for the contracting officer to verify the designation as a certified WOSB or EDWOSB small business in the Dynamic Small Business Search (DSBS) at https://web.sba.gov/pro-net/search/dsp_dsbs.cfm. The designation will also appear in the System for Award Management (SAM) after issuance of the final rule. Paragraphs (c) and (d) at FAR 19.1503, are proposed to be deleted. Paragraphs (e) and (f) at FAR 19.1503 are

redesignated as new paragraphs (c) and (d).

FAR 19.1504, Exclusions, is amended at paragraph (b) to replace Federal Prison Industries, Inc., and AbilityOne with “mandatory Government sources (see section 8.002)”, since both entities are referenced at FAR 8.002, Priorities for use of mandatory Government sources.

FAR 19.1505, Set-aside procedures, is amended to allow an offeror to submit an offer while awaiting certification under the WOSB Program. FAR 19.1505 is also amended to provide the contracting officer with guidance if an apparent successful offeror’s certification is pending under the WOSB Program. The contracting officer, prior to award, shall verify the apparently successful offeror is certified in SAM or DSBS. If the apparently successful offeror’s EDWOSB or WOSB certification is pending in DSBS, the contracting officer shall notify SBA’s Director/Government Contracting by email at WOSBpendingcertification@sba.gov, and request SBA’s eligibility determination.

Within 15 days from the date of the contracting officer’s notification, SBA will make a determination regarding the offeror’s status as an EDWOSB or WOSB eligible under the WOSB program.

If the contracting officer does not receive a determination from SBA within 15 days, the contracting officer, at their discretion, may provide SBA additional time to make a determination, or may proceed with award to the next highest evaluated offeror. The contracting officer shall not make award to an offeror who is not a certified EDWOSB or WOSB concern eligible under the WOSB program.

FAR 19.1506, Women-Owned Small Business Program sole-source awards, is amended to instruct a contracting officer that a sole-source award can only be made to a concern that has been certified pursuant to 13 CFR 127.300 as an EDWOSB or WOSB eligible under the WOSB Program. FAR 19.1506 is also amended to notify contracting officers that they shall not request an eligibility determination from SBA on pending certification applications for EDWOSB or WOSB sole-source awards.

Changes are proposed to FAR provision 52.212–3, Offeror Representations and Certifications—Commercial Items, to remove the representation for WOSB concerns and EDWOSB concerns eligible under the WOSB Program. This rulemaking also proposes to update the WOSB and EDWOSB joint venture provisions and clauses.

FAR clause 52.212–5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items, was also revised to make conforming changes.

Changes are proposed to FAR provision 52.219–1, Small Business Program Representations, to remove the representation for WOSB concerns and EDWOSB concerns eligible under the WOSB Program. This section also proposes to update the WOSB and EDWOSB joint venture provisions and clauses.

Changes are proposed to FAR clause 52.219–28, Post-Award Small Business Program Rerepresentation, to remove the rerepresentation for WOSB concerns and EDWOSB concerns eligible under the WOSB Program. This rulemaking also proposes to update the WOSB concern and EDWOSB concern joint venture clauses.

Changes are proposed to FAR clause 52.219–29, Notice of Set-aside for, or Sole-Source Award to, Economically Disadvantaged Women-owned Small Business Concerns, to delete the definition of WOSB Program Repository from the clause and to require that the EDWOSB concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300 as an EDWOSB. This section also proposes to delete text in the clause that the contracting officer will ensure the successful offeror has provided all required documents to the now defunct WOSB Program Repository. It adds text for EDWOSB set-aside procurements that offers are solicited only from certified EDWOSB concerns or concerns with a pending certification application in DSBS. This section also proposes to add text that for EDWOSB sole-source awards, offers are solicited only from certified EDWOSB concerns.

Changes are proposed to FAR clause 52.219–30, Notice of Set-aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program, to delete the definition of the now defunct WOSB Program Repository text from the clause. This rulemaking proposes to amend the clause to also add to the definition of WOSB concern eligible under the WOSB Program that the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300 as a WOSB. This rulemaking also proposes to delete text in the clause that the contracting officer will ensure the successful offeror has provided all required documents to the WOSB Program Repository. This rulemaking also proposes to amend the clause to add that offers are solicited only from

certified WOSB concerns or concerns with a pending certification application in DSBS for WOSB set-aside procurements. This rulemaking further proposes to amend the clause to add, for WOSB sole-source awards, that offers are solicited only from certified WOSB concerns.

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

This proposed rule amends the following provisions and clauses: Provision 52.212–3, clause 52.212–5, provision 52.219–1, clause 52.219–28, clause 52.219–29, clause 52.219–30. However, this proposed rule does not impose any new requirements on contracts at or below the SAT or for commercial items, including COTS items. The provisions and clauses continue to apply to acquisitions at or below the SAT and to acquisitions for commercial items, including COTS items.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

41 U.S.C. 1905 governs the applicability of laws to acquisitions at or below the SAT. Section 1905 generally limits the applicability of new laws when agencies are making acquisitions at or below the SAT, but provides that such acquisitions will not be exempt from a provision of law under certain circumstances, including when the FAR Council makes a written determination and finding that it would not be in the best interest of the Federal Government to exempt contracts and subcontracts in amounts not greater than the SAT from the provision of law. The FAR Council intends to make a determination to apply this statute to acquisitions at or below the SAT.

B. Applicability to Contracts for the Acquisition of Commercial Items, Including Commercially Available Off-The-Shelf (COTS) Items

41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial items, and is intended to limit the applicability of laws to contracts for the acquisition of commercial items. Section 1906 provides that if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items.

41 U.S.C. 1907 states that acquisitions of COTS items will be exempt from

certain provisions of law unless the Administrator for Federal Procurement Policy makes a written determination and finds that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of COTS items.

The FAR Council intends to make a determination to apply this statute to acquisitions for commercial items. The Administrator for Federal Procurement Policy intends to make a determination to apply this statute to acquisitions for COTS items.

C. Determinations

The purpose of this proposed rule is to implement section 825(a)(1) of the Carl Levin and Howard P. "Buck" McKeon National Defense Authorization Act for Fiscal Year 2015 and SBA's implementing regulation. Section 825 requires women-owned small business concerns and economically disadvantaged women-owned small business concerns to be certified to be eligible under the WOSB Program for set-aside or sole-source awards (see 13 CFR 127.300).

Section 825 is silent on the applicability of these requirements for acquisitions at or below the SAT and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1905 and its application to acquisitions at or below the SAT. Therefore, it does not apply to acquisitions at or below the SAT unless the FAR Council makes a written determination as provided at 41 U.S.C. 1905. Additionally, the law is silent on the applicability of this requirement to acquisitions of COTS items and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1907 and its application to acquisitions of COTS items. Therefore, it does not apply to acquisition of COTS items unless the Administrator for Federal Procurement Policy makes a written determination as provided at 41 U.S.C. 1907.

The law furthers the Administration's goal of simplifying the acquisition process and facilitating easier access to the Federal marketplace, in this case for women-owned small businesses and economically disadvantaged women-owned small businesses who make up an important component of the Government's industrial base. Exclusion of a large segment of Federal contracting, such as acquisitions at or below the SAT, and for acquisitions of COTS items, will limit the full implementation of these objectives.

Further, the primary FAR provisions and clauses implementing the certification of women-owned small businesses and economically disadvantaged women-owned small businesses in the WOSB Program are currently prescribed for use in COTS items.

Exclusion of acquisitions for COTS items would create confusion among contractors and the Federal contracting workforce.

For these reasons, it is in the best interest of the Federal Government to apply the requirements of the proposed rule to acquisitions at or below the SAT and to acquisitions of COTS items.

IV. Expected Impact of the Rule

As a result of this proposed rule, contracting officers will be required to check SAM or DSBS to determine if an EDWOSB or WOSB concern is certified or has a pending application for certification in DSBS instead of checking that all required documentation has been submitted to the now defunct WOSB Repository. Additionally, for set-aside procurements contracting officers will have to contact SBA should the apparently successful offeror have a pending application for certification. Within 15 days from the date of the contracting officer's notification, SBA will make a determination regarding the offeror's status as an EDWOSB or WOSB eligible under the WOSB program. If the contracting officer does not receive a determination from SBA within 15 days, the contracting officer at their discretion, may provide SBA additional time to make a determination, or may proceed with award to the next highest evaluated offeror. For EDWOSB or WOSB set-asides and sole-source awards, award can only be made to an EDWOSB or WOSB certified concern.

The changes in this proposed rule will affect internal Government operations, but not contractor operations. The required documentation (articles of incorporation, bylaws, stock ledgers or certificates, tax records, etc.) already exists. In addition, this information is already required to be provided either to third-party certifiers, governmental certifying entities, or to SBA through *certify.SBA.gov*. SBA expects WOSBs to see a reduction in burden because, under the prior WOSB Program Repository, SBA determined that the average time required to complete the process required by the WOSB Program Repository was two hours, whereas the use of the new certification process requires only one hour due to technological improvements.

The public cost associated with obtaining the WOSB or EDWOSB certification is accounted for under the SBA final rule implementing the Program certification requirements (85 FR 27660). In addition, the SBA final rule advises concerns that only a certified WOSB or EDWOSB may seek a specific sole-source requirement under the Program and that only a certified WOSB or EDWOSB or a concern that has a pending application for certification under the Program may submit an offer on a specific EDWOSB or WOSB set-aside requirement.

Given SBA's notice to small business concerns, the cost to the public associated with the FAR implementation of the SBA final rule is de minimis and is limited to the cost of regulatory familiarization, or the cost associated with reading this rule and understanding the new solicitation provision.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD, GSA, and NASA will send the rule and the "Submission of Federal Rules Under the Congressional Review Act" form to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This proposed rule is not anticipated to be a major rule under 5 U.S.C. 804.

VII. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. However, an initial regulatory flexibility analysis has

been performed and is summarized as follows:

DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a statutory requirement to certify Women-Owned Small Business Concerns (WOSBs) and Economically Disadvantaged Women-Owned Small Business Concerns (EDWOSBs) participating in the Procurement Program for Women-Owned Small Business Concerns (the Program). The certification requirement applies only to participants wishing to compete for set-aside or sole-source contracts under the Program. Once this rulemaking is effective, WOSBs and EDWOSBs that are not certified will not be eligible for contracts under the Program. Other WOSBs that do not participate in the Program may continue to self-certify their status, receive contract awards outside the Program, and count toward an agency's goal for awards to WOSBs.

The objective of this rulemaking is to implement section 825(a)(1) of the NDAA for Fiscal Year (FY) 2015, Public Law 113-291, which amended the Small Business Act to create a requirement that a concern be certified as a WOSB or EDWOSB by a Federal agency, a State government, the Small Business Administration (SBA), or a national certifying entity approved by SBA, in order to be awarded a set-aside or sole-source contract under the authority of section 8(m) of the Small Business Act. The legal basis for this rule is 15 U.S.C. 637(m)(2)(E).

This rulemaking will impact approximately 9,000–12,000 WOSBs. These businesses will have to apply to be certified as WOSBs or EDWOSBs to SBA or third-party certifiers in order to be eligible to be awarded any WOSB or EDWOSB set-aside contracts or sole-source awards under the WOSB program. However, SBA has minimized the impact on WOSBs by accepting certifications already conferred by SBA.

Data taken from FPDS-NG as of September 20, 2020, revealed that 7,198 awards were made to WOSB and EDWOSB contractors between FY 2017–2019. Of the 7,198 awards made, 553 or approximately 8% were WOSB and EDWOSB sole-source awards.

A further breakdown reveals that during FY 2017, a total of 3,150 awards were made to WOSB and EDWOSB contractors, with approximately 9 percent of these awards being sole-sourced. Of the 3,150 awards made, 244 were sole-sourced to WOSBs and 36 were sole-sourced to EDWOSBs.

During FY 2018, a total of 1,460 awards were made to WOSB and EDWOSB contractors, with approximately 17 percent of these awards being sole-sourced. Of the 1,460 awards made, 207 were sole-sourced to WOSBs and 42 were sole-sourced to EDWOSBs.

During FY 2019, a total of 2,588 awards were made to WOSB and EDWOSB, with approximately 9 percent of these awards being sole-sourced. Of the 2,588 awards made, 204 were sole-sourced to WOSBs and 20 were sole-sourced to EDWOSBs.

The costs to WOSBs for certification should be de minimis, because the required documentation (articles of incorporation,

bylaws, stock ledgers or certificates, tax records, etc.) already exists. In addition, this information is already required to be provided either to third-party certifiers, governmental certifying entities, or to SBA through *certify.gov*. SBA expects WOSBs to see a reduction in burden because under the prior WOSB Program Repository, SBA determined that the average time required to complete the process required by the WOSB Program Repository was two hours, whereas the use of the new certification program requires only one hour due to technological improvements.

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

The Small Business Administration currently collects information to carry out its statutory mandate to provide oversight of certification related to SBA's WOSB Federal Contract Program. (OMB Control Number 3245-0374, Certification for the Women-Owned Small Business Federal Contract Program). Additionally, third-party certifiers are required to provide SBA with quarterly reports that include the number of applications received, number of applications approved and denied, and other information that SBA determines may be helpful for ensuring that third-party certifiers are meeting their obligations or information or data that may be useful for improving the program.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches that would accomplish the stated objectives of the applicable statute.

Although this proposed rule may have a positive impact on small businesses, we do not expect it to have a significant economic impact on a substantial number of small entities.

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

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit comments separately and should cite 5 U.S.C. 610 (FAR case 2020-013) in correspondence.

VIII. Paperwork Reduction Act

The proposed rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

List of Subjects in 48 CFR Parts 2, 19, and 52

Government procurement.

William F. Clark,

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

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 2, 19, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 2, 19, and 52 continues to read as follows:

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

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 2. In section 2.101, in paragraph (b)(2) amend the definition of “Women-Owned Small Business (WOSB) Program” by:

■ a. In paragraph (1), remove the phrase “sole source” and add the phrase “sole-source” in its place;

■ b. In paragraph (2), remove the phrase “13 CFR part 127” and add the phrase “13 CFR part 127, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300” in its place; and

■ c. In paragraph (3), remove the phrase “(13 CFR part 127)” and add the phrase “, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300” in its place.

PART 19—SMALL BUSINESS PROGRAMS

■ 3. Amend section 19.308 by:

■ a. Removing from paragraph (d)(1)(ii) “women, when” and adding “women who are United States citizens, when” in its place;

■ b. Removing paragraph (d)(2);

■ c. Redesignating paragraph (d)(3) as (d)(2);

■ d. Removing from the newly designated paragraph (d)(2) “not a” and adding “not an” in its place;

■ e. Revising paragraph (f)(1);

■ f. Revising paragraphs (i)(3)(iii) and (i)(5)(iii);

■ g. Removing from paragraph (1)(2) “409 Third Street SW, Washington, DC 20416, or facsimile 202-205-6390” and adding “by email at *wosbprotest@sba.gov*” in its place; and

■ h. Removing from paragraph (1)(4) “facsimile 202-205-6873.”

The revisions read as follows:

19.308 Protesting a firm's status as an economically disadvantaged women-owned small business concern or women-owned small business concern eligible under the Women-Owned Small Business Program.

* * * * *

(f)(1) The contracting officer shall forward all protests to SBA. The protests are to be submitted to SBA's Director for Government Contracting by email at wosbprotest@sba.gov.

* * * * *

(i) * * *

(3) * * *

(iii) SBA will remove the concern's designation in the Dynamic Small Business Search (DSBS) as an EDWOSB or WOSB concern eligible under the WOSB Program. The concern shall not submit an offer as an EDWOSB concern or WOSB concern eligible under the WOSB Program, until SBA issues a decision that the ineligibility is resolved.

* * * * *

(5) * * *

(iii) SBA will remove the concern's designation in DSBS as an EDWOSB or WOSB concern eligible under the WOSB Program. The concern shall not submit an offer as an EDWOSB concern or WOSB concern eligible under the WOSB Program, until SBA issues a decision that the ineligibility is resolved or OHA finds the concern is eligible on appeal.

* * * * *

■ 4. Amend section 19.1500 by revising paragraph (c) to read as follows:

19.1500 General.

* * * * *

(c) An economically disadvantaged women-owned small business (EDWOSB) concern and a WOSB concern eligible under the WOSB Program are subcategories of "women-owned small business concern" as defined in section 2.101.

19.1501 [Removed and Reserved]

■ 5. Remove and reserve section 19.1501.

■ 6. Revise section 19.1503 to read as follows:

19.1503 Status.

(a) Status as an EDWOSB concern or WOSB concern eligible under the WOSB Program is determined by the Small Business Administration in accordance with 13 CFR part 127.

(b) For a WOSB that seeks a WOSB or EDWOSB set-aside or sole-source contract, the contracting officer shall verify that the offeror—

(1) Is registered in the System for Award Management (SAM); and

(2) Is designated as a certified EDWOSB or WOSB concern in the

Dynamic Small Business Search (DSBS) at https://web.sba.gov/pro-net/search/dsp_dsbs.cfm (see 19.1505(d) for set aside procedures). DSBS will provide SBA's certification status to SAM.

(c) If there is a decision issued by SBA as a result of a current eligibility examination finding that the concern did not qualify as an EDWOSB concern or WOSB concern eligible under the WOSB Program, the contracting officer may terminate the contract, and shall not exercise any option, or award further task or delivery orders. Agencies shall not count or include the award toward the small business goals for an EDWOSB concern or WOSB concern eligible under the WOSB Program and must update FPDS from the date of award to reflect the final SBA decision.

(d) A joint venture may be considered an EDWOSB concern or WOSB concern eligible under the WOSB Program if the EDWOSB or WOSB participant is certified in DSBS (see section 19.1505(d) for set aside procedures) and the joint venture meets the requirements of 13 CFR 127.506.

■ 7. Amend section 19.1504 by revising paragraph (b) to read as follows:

19.1504 Exclusions.

* * * * *

(b) Requirements that can be satisfied through award to mandatory Government sources (see section 8.002);

* * * * *

■ 8. Amend section 19.1505 by:

■ a. Revising paragraph (a)(2);

■ b. Redesignating paragraphs (f) and (g) as paragraphs (h) and (i);

■ c. Redesignating paragraph (d) as paragraph (g);

■ d. Adding paragraph (d);

■ e. Revising paragraph (e);

■ f. Adding paragraph (f); and

■ g. Revising newly redesignated paragraph (i) introductory text and (i)(1).

The revisions read as follows:

19.1505 Set-aside procedures.

(a) * * *

(2)(i) May set aside acquisitions exceeding the micro-purchase threshold for competition restricted to EDWOSB concerns when the acquisition is assigned a NAICS code in which SBA has determined that WOSB concerns are underrepresented in Federal procurement; or

(ii) May set aside acquisitions exceeding the micro-purchase threshold for competition restricted to WOSB concerns eligible under the WOSB Program when the acquisition is assigned a NAICS code in which SBA has determined that WOSB concerns are substantially underrepresented in

Federal procurement, as specified on SBA's website at <http://www.sba.gov/WOSB>.

* * * * *

(d) An offer is eligible for consideration under an EDWOSB or WOSB set-aside when the offeror—

(1) Qualifies as a small business concern under the size standard corresponding to the NAICS code assigned to the contract, and

(2)(i) For an EDWOSB set-aside, is certified pursuant to 13 CFR 127.300 as an EDWOSB or has a pending application for EDWOSB certification in the DSBS (see 13 CFR 127.504(a)), or

(ii) For a WOSB set-aside, is certified pursuant to 13 CFR 127.300 as an EDWOSB or WOSB, or has a pending application for EDWOSB or WOSB certification in the DSBS (see 13 CFR 127.504(a)).

(e) The contracting officer shall verify that offers received are eligible for consideration for award by checking to see if the EDWOSB or WOSB concern is designated as a certified concern or has a pending application for certification in DSBS.

(1) If the offeror is designated as certified or has a pending application for certification, proceed with the offer evaluation.

(2) Unless the offeror is designated as certified or has a pending application for certification, the offer is not eligible for award and shall be removed from consideration.

(f) Prior to award, the contracting officer shall verify the apparently successful offeror is certified in DSBS. If the apparently successful offeror's EDWOSB or WOSB certification is pending, the contracting officer shall notify SBA's Director/Government Contracting by email at WOSBpendingcertification@sba.gov, and request SBA's status determination. The contracting officer shall provide SBA with the offeror's name, unique entity identifier, type of set-aside, NAICS code, and solicitation number.

(1) Within 15 calendar days from the date of the contracting officer's notification, SBA will make a determination regarding the offeror's status as an EDWOSB or WOSB eligible under the WOSB program.

(2) If the contracting officer does not receive a determination from SBA within 15 calendar days, the contracting officer at their discretion, may provide SBA additional time to make a determination, or may proceed with award to the next highest evaluated offeror.

(3) The contracting officer shall not make award to an offeror who is not a

certified EDWOSB or WOSB concern eligible under the WOSB program.

* * * * *

(i) The SBA procurement center representative (PCR) may recommend use of the WOSB Program. If the contracting officer rejects a recommendation by SBA's PCR—

(1) The contracting officer shall notify the PCR as soon as practicable;

* * * * *

■ 9. Amend section 19.1506 by:

- a. Revising the section heading;
- b. In paragraphs (a) and (b) remove the phrase "sole source" and add the phrase "sole-source" in its place;
- c. Redesignating paragraph (d) as paragraph (e);
- d. Adding a new paragraph (d); and
- e. In newly redesignated paragraph (e), remove the phrase "sole source" and add the phrase "sole-source" in its place.

The revisions and addition read as follows:

19.1506 Women-Owned Small Business Program sole-source awards.

* * * * *

(d) A contracting officer shall only award a sole-source contract to a concern that has been certified pursuant to 13 CFR 127.300 as an EDWOSB or WOSB eligible under the WOSB program. Contracting officers shall not request a status determination from SBA on pending certification applications for EDWOSB or WOSB sole-source awards.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 10. Amend section 52.212–3 by:

- a. Revising the date of the provision;
- b. In paragraph (a), revise the definition "Women-owned small business (WOSB) concern eligible under the WOSB Program"; and
- c. Revising paragraphs (c)(6) and (7);

The revisions read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

Offeror Representations and Certifications—Commercial Items (DATE)

* * * * *

(a) * * *

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by,

one or more women who are citizens of the United States, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300.

* * * * *

(c) * * *

(6) *WOSB joint venture eligible under the WOSB Program.* The offeror represents that it is, is not a joint venture that complies with the requirements of 13 CFR part 127. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.]

(7) *Economically disadvantaged women-owned small business (EDWOSB) joint venture.* The offeror represents that it is, is not a joint venture that complies with the requirements of 13 CFR part 127. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.]

* * * * *

■ 11. Amend section 52.212–5 by:

- a. Revising the date of the clause;
- b. In paragraph (b), remove "[Contracting Officer check as appropriate.]" and add "[Contracting Officer check as appropriate.]" in its place;
- c. In paragraph (b)(23), remove "(SEP 2021)" and add "(DATE)" in its place; and
- d. In paragraph (b)(24), remove "(SEP 2021)" and add "(DATE)" in its place.

The revision reads as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (DATE)

* * * * *

■ 12. Amend section 52.219–1 by:

- a. Revising the date of the provision;
- b. In paragraph (a), revise the definitions "Economically disadvantaged women-owned small business (EDWOSB) concern" and "Women-owned small business (WOSB) concern eligible under the WOSB Program"; and
- c. Revising paragraphs (c)(4) and (5).

The revisions read as follows:

52.219–1 Small Business Program Representations.

* * * * *

Small Business Program Representations (DATE)

(a) * * *

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

* * * * *

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127) means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300.

* * * * *

(c) * * *

(4) *Women-owned small business (WOSB) joint venture concern eligible under the WOSB Program.* The offeror represents as part of its offer that it is, is not a joint venture that complies with the requirements of 13 CFR part 127. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.]

(5) *Economically disadvantaged women-owned small business (EDWOSB) joint venture.* The offeror represents as part of its offer that it is, is not a joint venture that complies with the requirements of 13 CFR part 127. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.]

* * * * *

- 13. Amend section 52.219–28 by revising the date of the clause and paragraphs (h)(4) and (5) to read as follows:

52.219–28 Post-Award Small Business Program Rerepresentation.

* * * * *

Post-Award Small Business Program Rerepresentation (DATE)

* * * * *

(h) * * *

(4) Women-owned small business (WOSB) joint venture eligible under the WOSB Program. The Contractor represents that it is, is not a joint venture that complies with the requirements of 13 CFR part 127. [*The Contractor shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture:* _____.]

(5) Economically disadvantaged women-owned small business (EDWOSB) joint venture. The Contractor represents that it is, is not a joint venture that complies with the requirements of 13 CFR part 127. [*The Contractor shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture:* _____.]

* * * * *

■ 14. Amend section 52.219–29 by:

- a. Revising the date of the clause;
- b. Revising paragraphs (a) and (c);
- d. In paragraph (d), remove “*Joint Venture*” and add “*Joint venture*” in its place.

The revisions read as follows:

52.219–29 Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns.

* * * * *

Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (DATE)

(a) *Definition. Economically disadvantaged women-owned small business (EDWOSB) concern*, as used in this clause, means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127, and is certified pursuant to 13 CFR 127.300 as an EDWOSB. It automatically qualifies as a women-owned small business (WOSB) concern eligible under the WOSB Program.

* * * * *

(c) *General.* (1) For EDWOSB set-aside procurements, offers are solicited only from certified EDWOSB concerns or EDWOSB concerns with a pending certification application in the Dynamic Small Business Search (DSBS).

(2) For EDWOSB sole-source awards, offers are solicited only from certified EDWOSB concerns.

(3) Offers received from other concerns will not be considered.

(4) Any award resulting from this solicitation will be made to a certified EDWOSB concern.

* * * * *

■ 15. Amend section 52.219–30 by:

- a. Revising the date of the clause;
- b. Revising paragraphs (a) and (c);
- d. In paragraph (d), remove “*Joint Venture*” and add “*Joint venture*” in its place.

The revisions read as follows:

52.219–30 Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program.

* * * * *

Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (DATE)

(a) *Definition. Women-owned small business (WOSB) concern eligible under the WOSB Program* (in accordance with 13 CFR part 127), as used in this clause, means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300 as a WOSB. A certified EDWOSB is automatically eligible as a certified WOSB.

* * * * *

(c) *General.* (1) For WOSB set-aside procurements, offers are solicited only from certified WOSB concerns eligible under the WOSB Program or WOSB concerns with a pending certification application status in the Dynamic Small Business Search (DSBS).

(2) For WOSB sole-source awards, offers are solicited only from certified WOSB concerns.

(3) Offers received from other concerns shall not be considered.

(4) Any award resulting from this solicitation will be made to a certified WOSB concern eligible under the WOSB Program.

* * * * *

[FR Doc. 2021–21343 Filed 10–6–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2020–0017; FF08E00000 FXES1111080000 212]

RIN 1018–BF94

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Tiehm’s Buckwheat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list *Eriogonum tiehmii* (hereafter Tiehm’s buckwheat), a plant species native to Nevada in the United States, as endangered under the Endangered Species Act of 1973, as amended (Act). If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Plants and extend the Act’s protections to the species.

DATES: We will accept any additional data, information, or comments received or postmarked on or before December 6, 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 a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 22, 2021.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter the docket number or RIN for this rulemaking (presented above in the document headings). For best results, do not copy and paste either number; instead, type the docket number or RIN into the Search box using hyphens. Then, click on the Search button. On the resulting page, in the 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.”

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R8–ES–2020–0017, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send any additional data, information, or

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

Availability of supporting materials: Our Species Status Assessment for Tiehm's buckwheat is available at <https://www.fws.gov/reno/> and at <https://www.regulations.gov> under Docket No. FWS-R8-ES-2020-0017.

FOR FURTHER INFORMATION CONTACT: Marc Jackson, Field Supervisor, U.S. Fish and Wildlife Service, Reno Ecological Services Field Office, 1340 Financial Boulevard, Suite 234, Reno, Nevada 89502; telephone 775-861-6337. 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. Under the Endangered Species Act of 1973, as amended ("Act"; 16 U.S.C. 1531 *et seq.*), if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register**, unless doing so is precluded by higher-priority actions and expeditious progress is being made to add and remove qualified species to or from the Lists of Endangered and Threatened Wildlife and Plants. The Service will make a determination on our proposal within 1 year. If there is substantial disagreement regarding the sufficiency and accuracy of the available data relevant to the proposed listing, we may extend the final determination for not more than six months. 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. Listing a species as an endangered or threatened species and designation of critical habitat can only be completed by issuing a rule.

What this document does. We propose to list Tiehm's buckwheat as an endangered species under the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or

educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that Tiehm's buckwheat is primarily at risk of extinction due to the destruction, modification, or curtailment of its habitat and range from mineral exploration and development; road development and off-highway vehicle (OHV) use; livestock grazing; nonnative, invasive plant species; and herbivory. Climate change may further influence the degree to which some of these threats (herbivory and nonnative invasive plant species), individually or collectively, may affect Tiehm's buckwheat. In addition, existing regulatory mechanisms may be inadequate to protect the species.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. 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 protections; 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 scientific data available and 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. In this proposed rule, we present our determination that designating critical habitat is prudent but not determinable at this time, and that we intend to propose designated critical habitat subsequently.

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 solicited reviews of the draft Species Status Assessment (SSA) for Tiehm's buckwheat. We sought the expert opinions of four independent specialists with expertise in botany, rare plant conservation, and plant ecology, and received responses from three of said experts. The purpose

of peer review of the SSA report is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. Comments from peer reviewers have been incorporated into our SSA as appropriate.

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 as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) Tiehm's buckwheat biology, distribution, and population size and trend, including:

(a) Biological or ecological requirements of the species, including habitat requirements for pollination, reproduction, and dispersal;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

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.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made "solely on the

basis of the best scientific and commercial data available.”

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 <https://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 <https://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 <https://www.regulations.gov>.

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the species is threatened instead of endangered, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species.

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 by news release 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

On October 7, 2019, we received a petition from the Center for Biological Diversity (CBD; CBD 2019, entire) requesting that Tiehm's buckwheat be listed as threatened or endangered, that critical habitat be concurrently designated for this species under the

Act, and that the petition be considered on an emergency basis. The Act does not provide for a process to petition for emergency listing; therefore, we evaluated the petition to determine if it presented substantial scientific or commercial information indicating that the petitioned action may be warranted. The Service published a 90-day finding on July 22, 2020 (86 FR 44265), stating that the petition presented substantial scientific or commercial information indicating that listing Tiehm's buckwheat may be warranted.

On September 29, 2020, CBD filed a complaint in the U.S. District Court for the District of Nevada against the Service alleging violations under the Administrative Procedure Act (5 U.S.C. 551 *et seq.*); CBD amended the complaint on October 14, 2020, to include a claim under the Act that the Service had missed the 1-year deadline of October 7, 2020, for issuing a 12-month finding for Tiehm's buckwheat. On April 21, 2021, the court issued a decision, and, in response to a stipulated request for a revised remedy order, on May 17, 2021, the court ordered the Service to deliver a 12-month finding on Tiehm's buckwheat to the **Federal Register** by May 31, 2021, and if warranted, a proposed listing rule by September 30, 2021, and if warranted and designating critical habitat is prudent and determinable, a proposed critical habitat determination by January 31, 2022 (or May 2, 2022, if the determination is deemed a “significant regulatory action” by the Office of Management and Budget). On May 20, 2021, the court issued an amended judgment, which serves as the final judgment in this case.

On June 4, 2021, the Service published a 12-month warranted finding (86 FR 29975) on the October 7, 2019, petition to list Tiehm's buckwheat. The Service now proposes to list Tiehm's buckwheat as an endangered species.

Supporting Documents

The Service prepared an SSA report for the Tiehm's buckwheat (Service, 2021 entire). The science provided in the SSA report is the basis for this proposed rule. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including past, present, and future impacts (both negative and beneficial) affecting the species. The SSA underwent independent peer review by scientists with expertise in botany, rare plant conservation, and plant ecology. The Service also sent the SSA report to three partner agencies, the Nevada Division of Forestry, the Nevada

Division of Natural Heritage (NDNH), and the Bureau of Land Management (BLM), for review. We received comments from NDNH and BLM. Comments received during peer and partner review were considered and incorporated into our SSA.

Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of Tiehm's buckwheat is presented in the SSA report (Service 2021, pp. 13–22). A summary of the SSA is provided below.

Species Description, Habitat, and Needs

Tiehm's buckwheat was first discovered in 1983 and described in 1985. All available taxonomic and genetic research information indicates that Tiehm's buckwheat is a valid and recognizable taxon and represents a distinct species. Tiehm's buckwheat is a low-growing perennial herb, with blueish gray leaves and pale, yellow flowers that bloom from May to June and turn red with age. Seeds ripen in late-June through mid-July (Revel 1985, pp. 277–278; Morefield 1995, pp. 6–7).

Tiehm's buckwheat occurs between 5,906 and 6,234 feet (ft; 1,800 and 1,900 meters (m)) in elevation and on all aspects with slopes ranging from 0–50 degrees (Ioneer 2020a, p. 5; Morefield 1995, p. 11). The species occurs on dry, upland sites, subject only to occasional saturation by rain and snow and is not found in association with free surface or subsurface waters (Morefield 1995, p. 11). Although there is no information on Tiehm's buckwheat's specific water needs during its various life stages (*i.e.*, dormant seed, seedling, juvenile, adult), it appears to be primarily dependent on occasional precipitation for its moisture supply (Morefield 1995, p. 11). Like most terrestrial plants, Tiehm's buckwheat requires soil for physical support and as a source of nutrients and water. Tiehm's buckwheat is a soil specialist specifically adapted to grow on its preferred soil type. The species is restricted to dry, open, relatively barren slopes with light-colored rocky clay soils derived from an uncommon formation of interbedded claystones, shales, tuffaceous sandstones, and limestones (Ioneer 2020a, p. 5; Morefield 1995, p. 10). Vegetation varies from pure stands of Tiehm's buckwheat to sparse associations with a few other low-growing herbs and grass species (Morefield 1995, p. 12). The abundance and diversity of arthropods (insects, mites, and spiders) observed in Tiehm's buckwheat subpopulations is especially high (1,898 specimens from 12 orders,

70 families, and 129 species were found in 2020) for a plant community dominated by a single plant species (McClinton *et al.* 2020, p. 11). Primary pollinator visitors to Tiehm's buckwheat include wasps, beetles, and flies (McClinton *et al.* 2020, p.18). Tiehm's buckwheat benefits from pollinator services and needs pollination to increase seed production.

Tiehm's buckwheat is a narrow-ranging endemic known only from one

population, comprising eight subpopulations, in the Rhyolite Ridge area of Silver Peak Range in Esmeralda County, Nevada. The single population of Tiehm's buckwheat is restricted to approximately 10 acres (4 hectares) across a 3-square-mile area, located entirely on public lands administered by BLM. The subpopulations are separated by a rural, unpaved, county road where subpopulations 1, 2, and 8

occur north of the road, and subpopulations 3, 4, 5, 6, and 7 occur south of the road (Figure 1). A 2019 survey estimated that the total Tiehm's buckwheat population is 43,921 individual plants (Table 1; Kuyper 2019, p. 2). Multiple survey efforts have not detected additional populations of the species.

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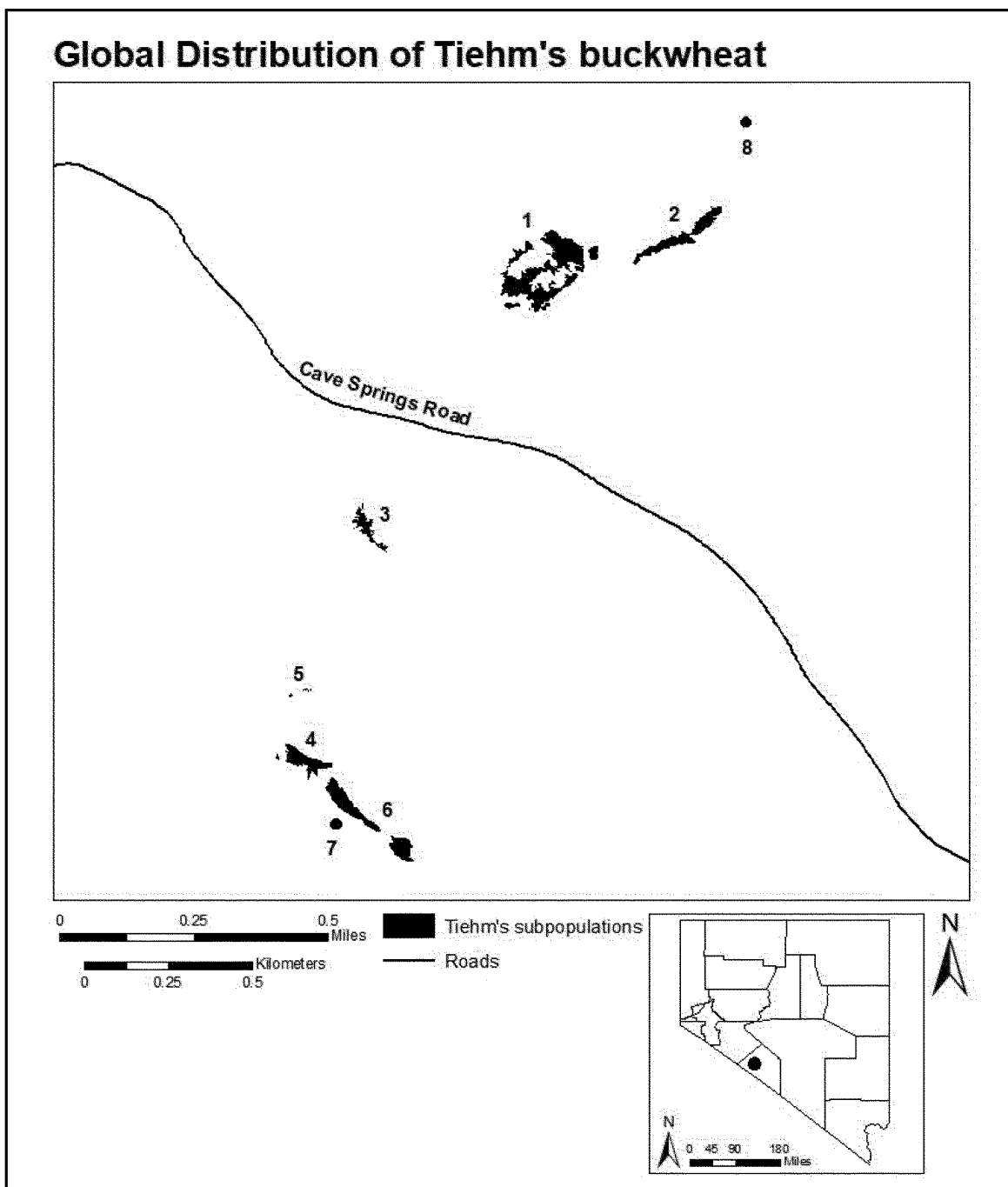


Figure 1—Global distribution of Tiehm’s buckwheat. The single population comprises eight subpopulations, indicated by the corresponding numbers on the map.

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TABLE 1—SUMMARY OF TIEHM’S BUCKWHEAT INDIVIDUALS AND OCCUPIED HABITAT

Population	Subpopulation	Estimated number of plants			Occupied habitat (acres)	
		1994 ^a	2008/2010 ^b	2019 ^c	2008/2010	2019
1	1	7,000+	15,380	9,240	4.71	4.81
	2	3,000+	4,000	4,541	1.17	1.56

TABLE 1—SUMMARY OF TIEHM’S BUCKWHEAT INDIVIDUALS AND OCCUPIED HABITAT—Continued

Population	Subpopulation	Estimated number of plants			Occupied habitat (acres)	
		1994 ^a	2008/2010 ^b	2019 ^c	2008/2010	2019
	3	500+	4,000	1,860	0.62	0.63
	4	500+	1,960	8,159	0.58	1.04
	5	15	100	^d 199	0.03	0.04
	6	6,000+	11,100	19,871	1.64	1.88
	7	n/a	n/a	^d 50	n/a	0.004
	8	n/a	n/a	^d 1	n/a	(*)
Total	17,015+	36,540	43,921	8.75	9.97

^aOcular estimate.

^bMethod employed: “Estimating Population Size Based on Average Central Density” (Morefield 2008, entire; Morefield 2010, entire).

^cMethod employed: Modified density sampling methodology in BLM technical reference “Sampling Vegetation Attributes” (BLM 1999, Appendix B) and “Measuring and Monitoring Plant Subpopulations” (Elzinga *et al.* 1998; Kuyper 2019, entire).

^dDirect count.

* (1 plant).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an endangered species as a species that is “in danger of extinction throughout all or a significant portion of its range” and a threatened species as a species that is “likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.” The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
- (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species’ continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term “threat” to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. These include actions or

conditions that have a direct or indirect impact as well as those that affect individuals through alteration of their habitat or resources. The term “threat” may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an “endangered species” or a “threatened species.” In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an “endangered species” or a “threatened species” only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term “foreseeable future,” which appears in the statutory definition of “threatened species.” Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term “foreseeable future” extends only so far into the future as the Service can reasonably determine that both the

future threats and the species’ responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. “Reliable” does not mean “certain”; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species’ likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species’ biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. It does, however, provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R8–ES–2020–

0017 on <https://www.regulations.gov> and at <https://www.fws.gov/reno/>.

To assess viability of the Tiehm's buckwheat, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic impacts. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

For the Tiehm's buckwheat to maintain viability, its populations or some portion thereof must be resilient. A number of factors influence the resiliency of Tiehm's buckwheat, including suitable habitat, abundance, and recruitment. Elements of the species' habitat that determine whether

the Tiehm's buckwheat population can grow to maximize habitat occupancy influence those factors, thereby influencing the resiliency of the population. These resiliency factors and habitat elements are discussed in detail in the SSA report (Service 2021, entire) and summarized here.

Summary of Biological Status and Threats

We reviewed the potential threats that could be affecting the Tiehm's buckwheat now and in the future. In this proposed rule, we will discuss only those threats in detail that could meaningfully impact the status of the species. Those threats that are not known to have effects on Tiehm's buckwheat, such as disease and overutilization for commercial and scientific purposes, are not discussed here, but are evaluated in the SSA report. The primary threats affecting the status of the Tiehm's buckwheat are physical alteration of habitat due to mineral exploration and development, road development and OHV use, livestock grazing, and nonnative, invasive plant species (all Factor A threats); herbivory (Factor C); and climate change (Factor E). Climate change may further influence the degree to which these threats, individually or collectively, may affect Tiehm's buckwheat. While we generally discuss these threats individually, threats can also occur simultaneously, thus additively affecting the resiliency of Tiehm's buckwheat. Where different individual threats occur at the same time and place, we will describe how they may interact with one another in the threats discussion below. Threats may be reduced through the implementation of existing regulatory mechanisms or other conservation efforts that benefit Tiehm's buckwheat and its habitat. We also summarize and discuss how the existing regulatory mechanisms (Factor D) address these threats.

Herbivory

The naturally occurring Tiehm's buckwheat population (represented by one population with eight subpopulations) and a seedling transplant experiment suffered detrimental herbivory in 2020. All of the naturally occurring subpopulations experienced greater than 50 percent damage or loss of individual plants, while almost all experimental transplants were lost to rodent herbivores in a 2-week period (Service 2020, pp. 29–33). An environmental DNA analysis (*i.e.*, trace DNA found in soil, water, food items, or other

substrates with which an organism has interacted) conducted on damaged Tiehm's buckwheat roots, nearby soils, and rodent scat strongly linked small mammal herbivory to the widespread damage and loss of the naturally occurring Tiehm's buckwheat population (Grant 2020, entire). This was the first time herbivory was documented on the species, although, prior to 2019, surveys of the population were infrequent. The significance of herbivory in the naturally occurring population depends not only on its frequency and intensity, but also on whether damaged plants can recover and survive, as we are uncertain if the species will be able to recover from this damage and loss. Rodent herbivore pressure precluded seedling survival in experimental plots. Further studies and monitoring need to be conducted to determine if management to reduce rodent herbivory is necessary to maintain Tiehm's buckwheat individuals and subpopulations, or if it was just a random catastrophic event that is not likely to occur on a regular basis.

The recent herbivory event that Tiehm's buckwheat experienced was extensive enough to compromise the long-term viability of individuals, subpopulations, and the overall population. One possibility for why this occurred is that climate changes are causing changes in moisture availability. Total precipitation was above average in the Rhyolite Ridge area from 2015 through 2019, whereas in 2020, it was significantly below average. Increases in precipitation are typically followed by increases in rodent populations (Randel and Clark 2010; entire; Gillespie *et al.* 2008, pp. 78–81; Brown and Ernest 2002, pp. 981–985; Beatley 1976, entire). This sudden shift from above average to below average precipitation may be what impacted the local rodent population at Rhyolite Ridge; a large rodent population was seeking water from whatever source was available and, in this case, found the shallow taproots of mature Tiehm's buckwheat plants (Boone 2020, entire; Morefield 2020, p. 12). If herbivory was driven by a water-stressed rodent population, future alteration of temperature and precipitation patterns may create climate conditions for this situation to happen again, resulting in further damage or loss of Tiehm's buckwheat individuals.

Mineral Exploration and Development

The specialized soils on which Tiehm's buckwheat occurs are high in lithium and boron, making this location of high interest for mineral

development. Trenches and mine shafts associated with mineral exploration and development have already impacted subpopulations 1, 2, 3, 4, and 6, resulting in the loss of some of the Tiehm's buckwheat habitat (Morefield 1995, p. 15). Future mineral exploration and development would be expected to result in similar or more detrimental impacts to the species. The BLM lands on which Tiehm's buckwheat grows are subject to the operation of the Mining Law of 1872, as amended (30 U.S.C. 22–54). Therefore, under BLM's regulations, operators may explore and cause a surface disturbance of up to 5 acres after an operator gives notice to BLM and waits 15 days (43 CFR 3809.21(a)). By contrast, if a listed species or designated critical habitat is present, an operator must submit a mining plan of operations and obtain BLM approval for any surface disturbance greater than casual use (43 CFR 3809.11(b)(6)).

In May 2020, Ioneer USA Corporation (Ioneer) submitted a plan of operations to BLM for the proposed Rhyolite Ridge lithium-boron project. The proposed project is awaiting BLM permitting and approval and, if permitted, would result in the complete loss of Tiehm's buckwheat habitat and subpopulations 4, 5, 6, and 7, even with the voluntary protection measures included in Ioneer's project proposal. The voluntary protection measures included in Ioneer's project proposal are summarized below in the Conservation Measures and Existing Regulatory Mechanisms section (protection measures are described more thoroughly in Service 2021, pp. 39–40, 46–47). The potential impact from the proposed project, combined with the loss resulting from the recent herbivory event, would reduce the total Tiehm's buckwheat population by 70 to 88 percent, or from 43,921 individuals to roughly 5,289–8,696 individuals, and remove 30 percent of its total habitat (2.96 ac (1.2 ha); Ioneer 2020a, Figure 4, p. 29). The number of individuals estimated to survive is represented by a range, because we do not know yet if the plants damaged from herbivory will be able to recover and survive. The low end of this range is based on permanent loss of damaged plants, while the high end represents conditions if all the herbivore-damaged plants recover. At the end of the project as proposed, areas previously occupied by Tiehm's buckwheat in subpopulations 4–7 would be underwater within the boundaries of a quarry lake (Ioneer 2020b, pp. 71–72). Ioneer is proposing to remove and salvage all remaining plants in subpopulations 4, 5, 6, and 7

(between 11,701–16,205 plants depending on if damaged plants recover from herbivory) and translocate them to another location. However, because Tiehm's buckwheat is a soil specialist and adjacent, unoccupied sites are not suitable for all early life-history stages, herbivore impacts on transplanted seedlings, and lack of testing and multiyear monitoring on the feasibility of transplanting the species, we are uncertain of the potential for success of translocation efforts.

Subpopulation 6 may be the most resilient of the eight Tiehm's buckwheat subpopulations because it has the most individuals, produces a higher average density of flowers (correlating to a higher seed output), supports high pollinator diversity, and supports a variety of size classes, including having the most individuals in the smallest size class indicating that this subpopulation is likely experiencing the most recruitment (Kuyper 2019, p. 3; Ioneer 2020a, pp. 7–8; McClinton *et al.* 2020, p. 23, 51). Loss of this subpopulation to the proposed Rhyolite Ridge lithium-boron project may have an immense impact on the overall resiliency and continued viability of the species, beyond just the numeric loss of redundancy and representation.

Rare plant species, like Tiehm's buckwheat, that have restricted ranges, specialized habitat requirements, and limited recruitment and dispersal, have a higher risk of extinction due to demographic uncertainty and random environmental events (Shaffer 1987, pp. 69–75; Lande 1993, pp. 911–927; Hawkins *et al.* 2008, pp. 41–42; Caicco 2012, pp. 93–94; Kaye *et al.* 2019, p. 2). Additionally, habitat fragmentation poses specific threats to species through genetic factors such as increases in genetic drift and inbreeding, together with a potential reduction in gene flow from neighboring individuals or subpopulations (Jump and Peñuelas 2005, pp. 1015–1016). The effects of habitat fragmentation from the proposed Rhyolite Ridge lithium-boron project on Tiehm's buckwheat may be compounded by the inherently poor dispersal of the species and its specific soil requirements.

Road Development and Off-Highway Vehicle Use

Ecological impacts of roads and ground-disturbing activities like OHV use include altered hydrology, pollution, sedimentation, silt and dust erosion and deposition, habitat fragmentation, reduced species diversity, and altered landscape patterns (Forman and Alexander 1998, entire; Spellerberg 1998, entire). OHV impacts

have occurred in subpopulation 1 (Caicco and Edwards 2007, entire; Donnelly and Fraga 2020, p. 1; Ioneer 2020a, p. 10) and can kill or damage individual plants and modify habitat through fragmentation and soil compaction. Mining and mineral exploration activities that grade, improve, and widen roads in the Rhyolite Ridge area may allow easier and greater access for OHVs and recreational use. Additionally, road development and increased vehicle traffic associated with the mine may create conditions that further favor the establishment of nonnative, invasive species within Tiehm's buckwheat habitat.

Ioneer's proposed Rhyolite Ridge lithium-boron project would construct and maintain service and haul roads within the Rhyolite Ridge area. Cave Springs Road (as seen on Figure 1) is currently maintained by Esmeralda County and bisects the Tiehm's buckwheat subpopulations. Realignment of this road is proposed to accommodate haul roads. It is expected that the rerouted road would be transferred to the county at closure, as an amendment to the county's existing right-of-way with BLM (Ioneer 2020b, p. 44). The expected amount of truck traffic associated with providing needed materials and supplies and product transport for the proposed project is anticipated to be 100 round trips per day, 365 days per year (Ioneer 2020b, p. 7).

Dust deposition, often a result of vehicle traffic on roads, negatively affects the physiological processes of plants including photosynthesis, reproduction, transpiration, water use efficiency, leaf hydraulic conductance, and stomatal disruption that impedes the ability of the stomata to open and close effectively (Hirano *et al.* 1995, pp. 257–260; Vardaka *et al.* 1995, pp. 415–418; Wijayratne *et al.* 2009, pp. 84–87; Lewis 2013, pp. 56–79; Sett 2017, entire). Physiological disruption to Tiehm's buckwheat individuals from dust generated from vehicular traffic associated with the proposed Rhyolite Ridge lithium-boron project would likely negatively affect the overall health and physiological processes of the population and of the subpopulations remaining (1, 2, 3, and 8) after full implementation of the proposed Rhyolite Ridge lithium-boron project.

Livestock Grazing

Livestock grazing has the potential to result in negative impacts to Tiehm's buckwheat individuals, subpopulations, and/or the population, depending on

factors such as stocking rate and season of use. Livestock grazing may result in direct impacts to individual Tiehm's buckwheat plants due to trampling of vegetation and soil disturbance (compaction) in ways that can render habitat no longer suitable to established plants, while also discouraging population recruitment (by discouraging seed retention, seed germination, and seedling survival). Patterns of soil disturbance associated with grazing also can create conditions conducive to the invasion of nonnative plant species (Young *et al.* 1972, entire; Hobbs and Huenneke 1992, p. 329; Loeser *et al.* 2007, pp. 94–95).

Tiehm's buckwheat occurs in the BLM Silver Peak livestock grazing allotment (BLM 1997, p. 15, Map 17). The Silver Peak allotment (NV00097) was authorized on September 9, 2020, with a 4-year term that expires on September 24, 2024 (BLM 2021a, entire). There are no grazing exclosures associated with Tiehm's buckwheat within this BLM allotment; therefore, the species may be exposed to the effects of livestock grazing described in the above paragraph. Although some Tiehm's buckwheat individuals may be impacted by this threat, current grazing damage to Tiehm's buckwheat has not been observed. There are currently 658 active AUMs (animal unit months) and 2,507 temporarily suspended AUMs associated with the Silver Peak allotment due to stocking water range improvements that have fallen out of repair.

Upon expiration of the Silver Peak allotment, BLM will consider reauthorization and/or changing the number of active AUMs. Range improvements are in progress, and additional AUMs may be returned on this allotment (Truax 2020, pers. comm.). However, grazing impacts could potentially increase in the future if additional AUMs are returned to this allotment.

Nonnative, Invasive Plant Species

Nonnative, invasive plant species could negatively affect Tiehm's buckwheat individuals, subpopulations, and/or the population through competition, displacement, and degradation of the quality and composition of its habitat (Gonzalez *et al.* 2008, entire; Simberloff *et al.* 2013, entire). Surveys of Tiehm's buckwheat conducted between 1994 and 2010 did not document any occurrences of nonnative, invasive species in its habitat (Morefield 1995, entire; Caicco and Edwards 2007, entire; Morefield 2008, entire; Morefield 2010, entire). However, saltlover (*Halogeton*

glomeratus) has since become established to some degree and is part of the associated plant community in all subpopulations of Tiehm's buckwheat (CBD 2019, pp. 20–21; Ioneer 2020a, pp. 9–10). Vehicles can carry the seeds of nonnative, invasive plant species into the area, and soil disturbances, such as mineral exploration activities, can encourage the spread of saltlover, which alters the substrate by making the soil more saline and less suitable as habitat for Tiehm's buckwheat.

Road development and vehicle traffic associated with the proposed mine as well as livestock grazing, which currently occurs within the Tiehm's buckwheat population as part of the BLM's Silver Peak allotment, may create conditions that further favor the establishment of nonnative, invasive species within Tiehm's buckwheat habitat. For example, Ioneer's Rhyolite Ridge lithium-boron project proposes to construct and operate a quarry, processing plant, overburden storage facility, spent ore storage facility, and access roads (Ioneer 2020b, p. 11). If the project is approved, and these ground-disturbing activities occur, there is a potential for increase in spread of nonnative, invasive plant species. However, this possible increase would depend on conditions associated with approval of the proposed project. Under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), BLM has the discretion to analyze best management practices to help reduce the likelihood that nonnative, invasive plant species are introduced and spread in Tiehm's buckwheat habitat.

Climate Change

The effects of climatic changes in the Great Basin depend largely on the interaction of temperature and precipitation. Temperatures in the Great Basin have increased over the past 100 years. Between 1895 and 2011, temperatures in the Great Basin have increased 1.2° to 2.5°F (0.7° to 1.4°C), with a greater increase in the southern Great Basin (where *Eriogonum tiehmii* occurs) than in the northern Great Basin (Snyder *et al.* 2019, p. 3). Temperatures are increasing more at night than during the day and more in winter than in summer, leading to fewer cold snaps, more heatwaves, fewer frosty days and nights, less snow, and earlier snowmelt (Snyder *et al.* 2019, p. 3; Padgett *et al.* 2018, p. 167; Abatzoglou and Kolden 2013, entire; Knowles *et al.* 2006, p. 4557; Mote *et al.* 2005, entire; Stewart *et al.* 2005, p. 1152). Although these observed trends provide information as to how climate has changed in the past,

climate models can be used to simulate and develop future climate projections.

Simulations using downscaled methods from 20 global climate models project mean average temperature during December, January, and February for the Rhyolite Ridge area to increase by 2.3°F (1.3°C) by 2060 and 3.4°F (1.9°C) by 2099 under moderate emission scenarios (RCP 4.5; Hegewisch and Abatzoglou (2020a). Under high emission scenarios (RCP 8.5), mean average temperatures during winter months increase by 3.6°F (2°C) by 2060 and 7.1°F (3.9°C) by 2099. Likewise, these models project maximum average temperatures during June, July, and August for the Rhyolite Ridge area to increase by 2.9°F (1.6°C) by 2060 and 4.1°F (2.3°C) by 2099 under moderate emission scenarios (RCP 4.5). Under high emission scenarios (RCP 8.5), maximum average temperatures during summer months increased by 4.6°F (2.6°C) by 2060 and 8.9°F (4.9°C) by 2099 (Hegewisch and Abatzoglou 2020a).

Additionally, simulations using these downscaling methods from multiple models project annual precipitation for the Rhyolite Ridge area to increase by 0.4 in (10.16 mm (milometers)) by 2060 and 0.6 in (15.24 mm) by 2099 under moderate emission scenarios (RCP 4.5). Under high emission scenarios (RCP 8.5), annual precipitation increases by 0.3 in (7.62 mm) by 2060 and 0.7 in (17.78 mm) by 2099 (Hegewisch and Abatzoglou 2020a). Total precipitation was above average in the Rhyolite Ridge area during the period 2015–2019, ranging from 6.1 to 8.7 in (15.5 to 22 cm) a year (Hegewisch and Abatzoglou 2020b). Whereas, in 2020, total average precipitation for the same area was 2.7 in (6.8 cm; Hegewisch and Abatzoglou 2020c).

Tiehm's buckwheat is adapted to dry, upland sites, subject only to occasional saturation by rain and snow. Increasing temperature can affect precipitation patterns. The fraction of winter precipitation (November–March) that falls as snow versus rain is declining in the western United States (Palmquist *et al.* 2016, pp. 13–16). When temperatures are cold enough to limit water losses from plant transpiration and soils are not frozen, shifts from snow to rain may have minimal impact on deep soil water storage. If rainfall replaces snow and temperatures are increased enough to thaw soils to stimulate plant growth and physiological activity earlier in the year, this scenario would result in less deep soil water recharge (*i.e.*, less soil water infiltration and more evaporation) and potential changes in plant community

composition (Huxman *et al.* 2005, entire).

Fire is a naturally occurring phenomenon that impacts the distribution and structure of vegetation (Willis 2017, p. 52). However, due to increasing temperatures and reductions in precipitation, the severity and frequency of wildfires is likely to increase (Snyder *et al.* 2019, p. 8; Comer *et al.* 2013, pp. 130–135; Chambers and Wisdom 2009, pp. 709–710). While the Great Basin is extremely prone to fires, with 14 million ac (5.6 million ha) burning in the last 20 years, there are no reported accounts of fire within Tiehm's buckwheat habitat or in the surrounding Rhyolite Ridge area (BLM 2020, entire). We currently do not have any data to indicate what level of effect wildfire could have on Tiehm's buckwheat; however, it could result in habitat loss or habitat fragmentation and/or remove Tiehm's buckwheat individuals.

The direct, long-term impact from climate change to Tiehm's buckwheat is yet to be determined. The timing of phenological events, such as flowering, are often related to environmental variables such as temperature. Large-scale patterns of changing plant distributions, flowering times, and novel community assemblages in response to rising temperatures and changing rainfall patterns are apparent in many vegetation biomes (Munson and Long 2017, entire; Willis 2017, pp. 44–49; Hawkins *et al.* 2008, entire; Burgess *et al.* 2007, entire; Parmesan 2006, entire). However, we do not know if or how climate change may alter the phenology of Tiehm's buckwheat or cause changes in pollinator behavior.

In summary, Tiehm's buckwheat is adapted to dry, upland sites, subject only to occasional saturation by rain and snow. Under climate change predictions, we anticipate alteration of precipitation and temperature patterns, as models forecast warmer temperatures and slight increases in precipitation. The timing and type of precipitation received (snow vs. rain) may impact plant transpiration and the soil water recharge needed by Tiehm's buckwheat. Additionally, variability in interannual precipitation combined with increasing temperatures, as recently seen from 2015 through 2020, may make conditions less suitable for Tiehm's buckwheat by bolstering local rodent populations. High rodent abundance combined with high temperatures and drought may have contributed to the large herbivore impacts in 2020 in both the transplant experiment and native population. Thus, climate change may exacerbate impacts from rodent

herbivory currently affecting this species and its habitat.

Conservation Measures and Regulatory Mechanisms

BLM

Tiehm's buckwheat is on the BLM Sensitive Species List (BLM 2008a, pp. 1–48). Although Tiehm's buckwheat is managed as a BLM sensitive species, BLM's regulations do not allow the agency to require conservation measures for sensitive species as a condition for exploring for, or developing minerals subject to disposal under the Mining Law of 1872, as amended (30 U.S.C. 22–54; Mining Law). Under BLM's handbook, the Silver Peak allotment permits grazing across 281,489 ac (113,915 ha) that also encompass the area occupied by Tiehm's buckwheat. Under the Federal Land Policy and Management Act of 1976, as amended (43 U.S.C. 1701 *et seq.*), BLM has the discretion to establish and implement special management areas, such as areas of critical environmental concern, to reduce or eliminate actions that adversely affect sensitive species, such as Tiehm's buckwheat. Although Tiehm's buckwheat is a BLM sensitive species, there are no special restrictions or terms and conditions regarding livestock use within the Silver Peak allotment where this species occurs nor are there any on the ground protections for Tiehm's buckwheat as a sensitive species. BLM has best management practices (BMPs) for invasive and nonnative species that focus on the prevention of further spread and/or establishment of these species (BLM 2008b, pp. 76–77). BMPs should be considered and applied where applicable to promote healthy, functioning native plant communities, or to meet regulatory requirements. BMPs include inventorying weed infestations, prioritizing treatment areas, minimizing soil disturbance, and cleaning vehicles and equipment (BLM 2008b, pp. 76–77). However, incorporation or implementation of BMPs is at the discretion of an authorized BLM officer.

In response to the recent herbivory event on Tiehm's buckwheat subpopulations, BLM has been monitoring the species biweekly. Photo plots were established near undamaged plants in subpopulations 1, 3, and 6 to help determine whether herbivory is continuing (Crosby 2020a, pers. comm.; Crosby 2020b, pers. comm.). Ocular estimates from the photo plots indicate that herbivory is not ongoing (Crosby 2020b, pers. comm.). Game cameras that were installed by BLM when damage to

the species was first reported were removed in mid-November 2020 but may be reinstalled if deemed necessary (Crosby 2020a, pers. comm.).

Ioneer

As part of the proposed Rhyolite Ridge lithium-boron project, Ioneer is developing a conservation plan for Tiehm's buckwheat to protect and preserve the continued viability of the species on a long-term basis. The conservation plan is in the early stages of development.

Ioneer has also implemented or proposed various protection measures for Tiehm's buckwheat. Ioneer funded the development of a habitat suitability model to identify additional potential habitat for Tiehm's buckwheat through field surveys (Ioneer 2020a, p. 12). In addition, a demographic monitoring program was initiated in 2019 to detect and document trends in population size, acres inhabited, size class distribution, and cover with permanent monitoring transects established in subpopulations 1, 2, 3, 4, and 6 (Ioneer 2020a, p. 16). Ioneer also funded collection of Tiehm's buckwheat seed in 2019 (Ioneer 2020a, pp. 13–14). Some of this seed was used by the University of Nevada, Reno, for a propagation trial and transplant study (Ioneer 2020a, p. 14). The remainder of this seed is in long-term storage at Rae Selling Berry Seed Bank at Portland State University (Ioneer 2020a, p. 13). Ioneer's proposed plans include avoiding subpopulations 1, 2, 3, and 8 (5,289 plants; Ioneer 2020a, p. 11), installing fences and signage around subpopulations 1 and 2 (Ioneer 2020a, p. 11), and removing and salvaging all remaining plants in subpopulations 4, 5, 6, and 7 (16,205–11,701 plants depending on if damaged plants recover from herbivory) and translocating them to another location (Ioneer 2020a, p. 15). However, the proposed project may or may not be permitted by BLM, thus these protection measures may or may not be fully implemented.

Summary of Current Condition

Data about the Tiehm's buckwheat population are sparse, as research and monitoring to better understand the species are still in their infancy (Grant 2020, entire; Ioneer 2020a, pp. 11–18; McClinton *et al.* 2020, entire; Service 2020, entire). As a result, little is known about subpopulation connectivity and dispersal (*i.e.*, gene-flow) and recruitment and/or seedling establishment, to inform population trend. Further studies and monitoring need to be conducted to determine if management to reduce herbivory is necessary to maintain Tiehm's

buckwheat individuals and subpopulations, or if the 2020 event was just a random catastrophic event that is not likely to occur on a regular basis.

Globally, Tiehm's buckwheat is known from 8 subpopulations that make up a single population (Table 1). Surveys have not detected additional populations of Tiehm's buckwheat. Tiehm's buckwheat substantially contributes to supporting the high abundance and diversity of arthropods and pollinators found in the Rhyolite Ridge area. A specific set of soil conditions are required for the growth of Tiehm's buckwheat, as the species is specifically adapted to grow on its preferred soil type (Ioneer 2020a, p. 5; Morefield 1995, p. 10).

Tiehm's buckwheat occurs entirely on 10 ac (4 ha) of Federal lands with sparse associations of other plant species. Rare plant species, like Tiehm's buckwheat, that have restricted ranges, specialized habitat requirements, and limited recruitment and dispersal have a higher risk of extinction due to demographic uncertainty and random environmental events. Under current conditions, primary threats to the species include mineral exploration and development, road development and OHV use, livestock grazing, nonnative, invasive plant species, herbivory, and climate change. Many of the threats currently affecting the species have the potential to work in combination. For example, mineral exploration, road development and OHV use, and livestock grazing can introduce nonnative, invasive plant species, which in turn can directly compete with and displace Tiehm's buckwheat within its habitat. With only one population (8 subpopulations), the risks to a small plant population like Tiehm's buckwheat include losses in reproductive individuals, declines in seed production and viability, loss of pollinators, loss of genetic diversity, and Allee effects (Willis 2017, pp. 74–77; Berc *et al.* 2007, entire; Eisto *et al.* 2000, pp. 1418–1420) which will impact a species that already has very limited redundancy and representation.

Determination of Tiehm's Buckwheat Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines endangered species as a species "in danger of extinction throughout all or a significant portion of its range," and threatened species as a species "likely to become an endangered species within the foreseeable future throughout all or

a significant portion of its range." The Act requires that we determine whether a species meets the definition of endangered species or threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we found that the population occurs in an extremely small area, has specialized habitat requirements, and has limited recruitment and dispersal. Our analysis revealed that the species is vulnerable to ongoing and future threats that affect both individual plants and their habitat.

We have carefully assessed the best scientific and commercial information available regarding the current and future threats to Tiehm's buckwheat. We considered the five factors identified in section 4(a)(1) of the Act in determining whether Tiehm's buckwheat meets the definition of an endangered species (section 3(6)) or threatened species (section 3(20)). We find that Tiehm's buckwheat is in danger of extinction due to the present or threatened destruction, modification, or curtailment of its habitat or range including habitat loss and degradation due to mineral exploration and development, road development and OHV use, livestock grazing, and nonnative, invasive plant species (all Factor A threats); herbivory (Factor C); and climate change (Factor E). Of these, we consider mineral exploration and development and herbivory to be the greatest threats to Tiehm's buckwheat. The existing regulatory mechanisms (Factor D) are inadequate to protect the species from these threats. We did not identify threats to the continued existence of Tiehm's buckwheat due to overutilization for commercial, recreational, scientific, or educational purposes (Factor B).

In 2020, a detrimental herbivory event caused greater than 50 percent damage or loss of individual Tiehm's buckwheat plants across all subpopulations. Cumulative impacts from the herbivory and the proposed Rhyolite Ridge lithium-boron project (if permitted by BLM) would reduce the total Tiehm's buckwheat population by 70 to 88

percent, or from 43,921 individuals to roughly 5,289–8,696 individuals as we do not know yet if damaged plants will be able to recover and survive or if translocating plants is feasible. Road development and vehicle traffic associated with the proposed mine as well as livestock grazing may further affect the overall health and physiological processes of individual Tiehm's buckwheat plants and create conditions that further favor the establishment of nonnative, invasive species within the species' habitat. Increased temperatures and alteration of precipitation patterns due to climate change may impact plant transpiration and soil water recharge needed by Tiehm's buckwheat, as well as bolstering local rodent populations. High rodent abundance combined with high temperatures and drought may have contributed to the herbivore impacts in 2020.

We find that Tiehm's buckwheat is in danger of extinction throughout all of its range due to the severity and immediacy of threats currently impacting the species now and those which are likely to occur in the near term. We find that a threatened species status is not appropriate because the threats are severe and imminent, and Tiehm's buckwheat is in danger of extinction now, as opposed to likely to become endangered in the future. Therefore, on the basis of the best available scientific and commercial information, we propose listing Tiehm's buckwheat as an endangered species in accordance with sections 3(6), 3(20), and 4(a)(1) of the Act.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We have determined that the Tiehm's buckwheat is in danger of extinction throughout all of its range and accordingly did not undertake an analysis of any significant portion of its range. Because the Tiehm's buckwheat warrants listing as endangered throughout all of its range, our determination is consistent with the decision in *Center for Biological Diversity v. Everson*, 2020 WL 437289 (D.D.C. Jan. 28, 2020), in which the court vacated the aspect of the Final Policy on Interpretation of the Phrase "Significant Portion of Its Range" in the Endangered Species Act's Definitions of "Endangered Species" and "Threatened Species" (79 FR 37578; July 1, 2014) that provided the Service does not

undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the Tiehm's buckwheat meets the Act's definition of an endangered species. Therefore, we propose to list the Tiehm's buckwheat as an endangered species in accordance with sections 3(6), and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public within 30 days of a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan

also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened ("downlisting") or removal from protected status ("delisting"), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (<https://www.fws.gov/endangered>), or from our Reno Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Nevada could be eligible for Federal funds to implement management actions that promote the protection or recovery of the Tiehm's buckwheat. Information on our grant programs that are available to aid species recovery can be found at: <https://www.fws.gov/grants>.

Although the Tiehm's buckwheat is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part

402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by BLM or other Federal agencies (or permitted or funded by a Federal agency).

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered plants. The prohibitions of section 9(a)(2) of the Act, codified at 50 CFR 17.61, make it illegal for any person subject to the jurisdiction of the United States to: Import or export; remove and reduce to possession from areas under Federal jurisdiction; maliciously damage or destroy on any such area; remove, cut, dig up, or damage or destroy on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law; deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity; or sell or offer for sale in interstate or foreign commerce an endangered plant. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered plants under certain circumstances. Regulations governing permits are codified at 50 CFR 17.62. With regard to endangered plants, a permit may be issued for scientific purposes or for enhancing the propagation or survival of the species. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR

34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) OHV or other vehicle use on existing roads and trails in compliance with the BLM Tonopah Field Office's resource management plan.

(2) Recreational use with minimal ground disturbance (*e.g.*, hiking, walking).

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act if they are not authorized in accordance with applicable law; this list is not comprehensive:

(1) Unauthorized handling, removing, trampling, or collecting of the Tiehm's buckwheat on Federal land; and

(2) Removing, cutting, digging up, or damaging or destroying the Tiehm's buckwheat in knowing violation of any law or regulation of the State of Nevada or in the course of any violation of a State criminal trespass law.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Reno Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

II. 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 that are:

(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. Such designation also does not allow the government or public to access private lands. Such 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 and commercial 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, 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. The implementing regulations at 50 CFR 424.12(b)(2) further delineate unoccupied critical habitat by setting out three specific parameters: (1) When designating critical habitat, the Secretary will first evaluate areas occupied by the species; (2) the Secretary will consider unoccupied areas to be essential only where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; and (3) 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 from the SSA report and 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.

As the regulatory definition of "habitat" indicates (50 CFR 424.02), 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 the 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, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Critical Habitat Prudence 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.

As discussed earlier, there is currently no threat of collection or vandalism identified for this species under Factor B, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA report and proposed listing determination for the Tiehm's buckwheat, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to Tiehm's buckwheat 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 enumerated in our regulations at 50 CFR 424.12(a)(1) have been met and because the Secretary has not identified other circumstances for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for Tiehm's buckwheat.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for Tiehm's buckwheat 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."

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. A careful assessment of the economic impacts that may occur due to a critical habitat designation is still ongoing, and we are in the process of working with the States and other partners in acquiring the complex information needed to perform that assessment. Therefore, the information sufficient to perform a required analysis of the impacts of the designation is lacking. For this reason, we conclude that the designation of critical habitat for the Tiehm's buckwheat is not determinable at this time.

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)); however, as described further in Previous Federal Actions, we are subject to a District of Nevada court order to submit to the **Federal Register** a proposed critical habitat determination by January 31, 2022 (or May 2, 2022 if the determination is deemed a "significant regulatory action" by the Office of Management and Budget).

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.

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 in connection with regulations adopted pursuant to section 4(a) of 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. At this time, we are not aware of Tribal lands occurring within the range of the Tiehm’s buckwheat.

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 Reno

Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the U.S. Fish and Wildlife Service’s Species Assessment Team and the Reno Ecological Services Field Office.

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 § 17.12(h), the List of Endangered and Threatened Plants, by adding an entry for “*Eriogonum tiehmii* (Tiehm’s buckwheat)” in alphabetical order under Flowering Plants to read as set forth below:

§ 17.12 Endangered and threatened plants.

* * * * *
(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
FLOWERING PLANTS				
* <i>Eriogonum tiehmii</i>	* Tiehm’s buckwheat	* Wherever found	* E	* [Federal Register citation when published as a final rule]
* 	* 	* 	* 	*

Martha Williams,
Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–21651 Filed 10–6–21; 8:45 am]
BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 300**

[Docket No. 210929–0202]

RIN 0648–BI79

International Fisheries; Western and Central Pacific Fisheries for Highly Migratory Species; Fish Aggregating Device Design Requirements in Purse Seine Fisheries, IMO Number Requirements, and Bycatch Restrictions

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS seeks comments on this proposed rule issued under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFC Implementation Act). The proposed rule would implement recent decisions of the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC or Commission) on fish aggregating device (FAD) design requirements, International Maritime Organization (IMO) number requirements, and bycatch restrictions for sharks and rays. This action is necessary to satisfy the obligations of the United States under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention), to which it is a Contracting Party. The proposed rule would apply to owners and operators of U.S. fishing vessels used for commercial fishing for highly migratory species (HMS) in the area of application of the Convention.

DATES: Comments on the proposed rule must be submitted in writing by November 8, 2021.

ADDRESSES: You may submit comments on the proposed rule and the regulatory impact review (RIR) prepared for the proposed rule, identified by NOAA–NMFS–2021–0068, by any of the following methods:

- *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA–NMFS–2021–0068 in the Search box. Click on the “Comment” icon,

complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Michael D. Tosatto, Regional Administrator, NMFS, Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

- *Fax:* (808) 725–5215; Attn: Michael D. Tosatto.

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

An initial regulatory flexibility analysis (IRFA) prepared under authority of the Regulatory Flexibility Act is included in the Classification section of the **SUPPLEMENTARY INFORMATION** section of this document.

Copies of the RIR and the Environmental Assessment are available at www.regulations.gov or may be obtained from Michael D. Tosatto, Regional Administrator, NMFS PIRO (see **ADDRESSES** above).

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to PIRO at the address listed above and to www.reginfo.gov/public/do/PRAMain.

FOR FURTHER INFORMATION CONTACT: Emily Crigler, NMFS PIRO, 808–725–5036.

SUPPLEMENTARY INFORMATION:**Background**

The Convention focused on the conservation and management of fisheries for HMS. The objective of the Convention is to ensure, through effective management, the long-term conservation and sustainable use of HMS in the Western and Central Pacific Ocean (WCPO). To accomplish this objective, the Convention established the Commission, which includes Members, Cooperating Non-members, and Participating Territories (collectively referred to here as “members”). The United States is a Member. American Samoa, Guam, and the Commonwealth of the Northern

Mariana Islands (CNMI) are Participating Territories.

As a Contracting Party to the Convention and a Member of the Commission, the United States implements, as appropriate, conservation and management measures and other decisions adopted by the Commission. The WCPFC Implementation Act (16 U.S.C. 6901 *et seq.*), authorizes the Secretary of Commerce, in consultation with the Secretary of State and the Secretary of the Department in which the United States Coast Guard is operating (currently the Department of Homeland Security), to promulgate such regulations as may be necessary to carry out the obligations of the United States under the Convention, including the decisions of the Commission. The WCPFC Implementation Act further provides that the Secretary of Commerce shall ensure consistency, to the extent practicable, of fishery management programs administered under the WCPFC Implementation Act and the Magnuson-Stevens Fishery Conservation and Management Act (MSA; 16 U.S.C. 1801 *et seq.*), as well as other specific laws (see 16 U.S.C. 6905(b)). The Secretary of Commerce has delegated the authority to promulgate regulations under the WCPFC Implementation Act to NMFS. A map showing the boundaries of the area of application of the Convention (Convention Area), which comprises the majority of the WCPO, can be found on the WCPFC website at: www.wcpfc.int/doc/convention-area-map.

The United States is also a member of the Inter-American Tropical Tuna Commission (IATTC). The convention areas for the IATTC and WCPFC overlap in the Pacific Ocean waters within a rectangular area bounded by 50° S latitude, 4° S latitude, 150° W longitude, and 130° W longitude (“overlap area”).

Historically, regulations implementing the conservation measures adopted by the IATTC (50 CFR part 300, subpart C) and the WCPFC (50 CFR part 300, subpart O) both applied to U.S. vessels fishing for HMS in the overlap area. In 2012, the IATTC and the WCPFC adopted recommendations/decisions under which members with vessels listed in both WCPFC Record of Fishing Vessels (Record) and IATTC Regional Vessel Register List (Register) would decide which of the two commissions’ decisions those vessels would operate under when fishing in the overlap area.¹

¹ See IATTC Recommendation C–12–11, “IATTC–WCPFC Overlap Area,” and WCPFC decision documented in “Summary Report of the Ninth

In 2020, NMFS published a rule (85 FR 37376; June 22, 2020) adjusting NMFS regulations implementing IATTC resolutions that apply in the overlap area, and adjusting NMFS regulations implementing WCPFC conservation and management measures that place limits or restrictions on catch, fishing effort, and bycatch mitigation to no longer apply in the overlap area (2020 overlap rule). In this proposed rule, NMFS proposes to follow the basis established in the 2020 overlap rule, so that the WCPFC management measures which would implement limits or restrictions on catch, fishing effort, and bycatch mitigation would not apply in the overlap area.

Measures To Be Implemented

This proposed rule includes implementation of specific provisions of four recent WCPFC decisions (CMM 2018–01, “Conservation and Management Measure for Bigeye, Yellowfin and Skipjack Tuna”; CMM 2018–06, “Conservation and Management Measure for WCPFC Record of Fishing Vessels and Authorisation to Fish”; CMM 2019–04, “Conservation and Management Measure for Sharks”; and CMM 2019–05, “Conservation and Management Measure on Mobulid Rays”).

The first decision, Conservation and Management Measure (CMM) 2018–01, “Conservation and Management Measure for Bigeye, Yellowfin, and Skipjack Tuna in the Western and Central Pacific Ocean,” was adopted by the Commission at its fifteenth regular annual session, in December 2018. The measures in CMM 2018–01 continue to be in force until February 15, 2022, per CMM 2020–01. The purpose of CMM 2018–01, and its predecessor measures, is to ensure the sustainability of the stocks of bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), and skipjack tuna (*Katsuwonus pelamis*) in the WCPO until the establishment of specific harvest strategies for those stocks. CMM 2018–01 is similar in many respects to its predecessor WCPFC conservation and management measures for tropical tunas, and NMFS has already implemented most provisions of CMM 2018–01 through prior rulemakings (see regulations at 50 CFR 300.223 and 50 CFR 300.224).

The proposed rule would implement the provisions of CMM 2018–01 regarding non-entangling FADs for purse seine fishing vessels. Paragraph

19 of CMM 2018–01 includes the following FAD specifications, in order to reduce the risk of entanglement of sharks, sea turtles or any other species, to be implemented by January 1, 2020:

- The floating or raft part (flat or rolled structure) of the FAD can be covered or not. To the extent possible the use of mesh net should be avoided. If the FAD is covered with mesh net, it must have a stretched mesh size less than 7 centimeters (cm) (2.5 inches) and the mesh net must be well wrapped around the whole raft so that there is no netting hanging below the FAD when it is deployed.

- The design of the underwater or hanging part (tail) of the FAD should avoid the use of mesh net. If mesh net is used, it must have a stretched mesh size of less than 7 cm (2.5 inches) or tied tightly in bundles or “sausages” with enough weight at the end to keep the netting taut down in the water column. Alternatively, a single weighted panel (less than 7 cm (2.5 inches) stretched mesh size net or solid sheet such as canvas or nylon) can be used.

The second decision, CMM 2018–06, “Conservation and Management Measure for WCPFC Record of Fishing Vessels and Authorisation to Fish,” includes an amendment that expands the requirement to obtain an IMO number to smaller vessels used for commercial fishing for HMS in the Convention Area. The CMM states that effective April 1, 2020, members “shall ensure that all their motorized inboard fishing vessels of less than 100 [gross registered tonnage] GRT (or 100 GRT) down to a size of 12 meters in length overall (LOA), authorized to be used for fishing in the Convention Area beyond the flag [members] area of national jurisdiction have an IMO or LR issued²”. The existing requirement to obtain an IMO number, implemented by NMFS, applies to vessels that are at least 100 GRT (see 50 CFR 300.217(c)). This proposed rule would expand the requirement to vessels less than 100 GRT down to a size of 12 meters LOA.

The third decision, CMM 2019–04, “Conservation and Management Measure for Sharks,” combines and replaces five management measures related to sharks that had previously been adopted by the Commission (CMM 2010–07, “Conservation and Management Measure for Sharks”; CMM

2011–04, “Conservation and Management Measure for Oceanic Whitetip Sharks”; CMM 2012–04, “Conservation and Management Measure on the Protection of Whale Sharks from Purse Seine Operations”; CMM 2013–08, “Conservation and Management Measure for Silky Sharks”; and CMM 2014–05, “Conservation and Management Measure for Sharks”). The measure and all of its provisions became effective November 1, 2020. Most of the provisions of CMM 2019–04 have already been promulgated through existing U.S. regulations (50 CFR 300.226; 50 CFR 300.223(g) and (h)), which implemented prior WCPFC decisions. However, there are two new provisions in the measure. The regulations at 50 CFR 300.226 prohibit the retention, transshipment, storage, or landing of the oceanic whitetip shark (*Carcharhinus longimanus*) and the silky shark (*Carcharhinus falciformis*), and require the release of oceanic whitetip shark and silky shark as soon as possible after the shark is caught and brought alongside the vessel. CMM 2019–04 includes an amendment that would allow for an exemption for purse seine vessels in cases where an oceanic whitetip shark or silky shark are not seen during fishing operations and are delivered into the vessel hold. Paragraph 20(3) of CMM 2019–04 states that, “in the case of oceanic whitetip shark and silky shark that are unintentionally caught and frozen as part of a purse seine vessels’ operation, the vessel must surrender the whole oceanic whitetip shark and silky shark to the responsible governmental authorities or discard them at the point of landing or transshipment.” Paragraph 20(3) also specifies that “[o]ceanic whitetip shark and silky shark surrendered in this manner may not be sold or bartered but may be donated for purpose of domestic human consumption.” CMM 2019–04 also includes an amendment that requires that sharks be hauled alongside the vessel before being cut free in order to facilitate species identification. However, the provision only applies when an observer or electronic monitoring camera is present. This proposed rule would implement the above listed provisions of CMM 2019–04.

CMM 2019–04 also includes a provision requiring that vessels are made aware of proper handling and release techniques for sharks. The WCPFC has adopted recommended guidelines for the safe release of sharks; however, the WCPFC guidelines are non-binding. Because use of the best

Regular Session of the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean,” Manila, Philippines, 2–6 December, 2012, paragraph 80.

² An IMO number is the unique number issued for a vessel under the ship identification number scheme established by the International Maritime Organization or, for vessels that are not strictly subject to that scheme, the unique number issued by the administrator of that scheme using the scheme’s numbering format, sometimes known as a Lloyd’s Register number or LR number.

handling practices is not a binding obligation, NMFS does not intend to require their use in this proposed rule. The WCPFC guidelines are available to vessel owners and operators at <https://www.wcpfc.int/doc/supplcmm-2010-07/best-handling-practices-safe-release-sharks-other-whale-sharks-and>.

The fourth decision, CMM 2019–05, “Conservation and Management Measure on Mobulid Rays Caught in Association with Fisheries in the WCPFC Convention Area,” was adopted by the Commission at its sixteenth regular annual session in December 2019. The main objective of CMM 2019–05 is to ensure the conservation of mobulid rays (*i.e.*, the family Mobulidae, which includes manta rays and devil rays (*Mobula* spp.)) by reducing incidental take and mortalities in the Convention Area. The measure, which became effective on January 1, 2021, requires that members: (1) Prohibit targeted fishing or intentional setting on mobulid rays in the Convention Area; (2) prohibit vessels from retaining on board, transshipping, or landing any part or whole carcass of mobulid rays caught in the Convention Area; (3) require vessels to promptly release mobulid rays, alive and unharmed, to the extent practical, as soon as possible and in a manner that will result in the least possible harm to the individuals captured; (4) provide for an exemption in cases where a mobulid ray is unintentionally caught and frozen as part of a purse seine vessel’s operation; and (5) require that vessels allow for observers to collect biological samples of mobulid rays that are dead at haul-back. This proposed rule would implement the above listed provisions of CMM 2019–05.

CMM 2019–05 also includes a provision requiring that vessel owners and operators are made aware of proper handling and release guidelines for mobulid rays. The measure includes best handling practices for the safe release of mobulid rays, and states that members should encourage their vessels to use them. However, because use of the best handling practices is not a binding obligation, NMFS does not intend to require their use in this proposed rule. The WCPFC guidelines are available to vessel owners and operators <https://www.wcpfc.int/doc/supplcmm-2010-07/best-handling-practices-safe-release-mantas-and-mobulids>.

Proposed Action

Under the proposed rule, the restrictions and requirements described in the Commission decisions above would apply to U.S. vessels used for

commercial fishing for HMS on the high seas and in exclusive economic zones (EEZs) in the Convention Area. NMFS is proposing to follow the basis established in the 2020 overlap rule, as noted above, so that the WCPFC management measures which would place limits or restrictions on catch, fishing effort, and bycatch mitigation would not apply in the overlap area. Following the approach used in the 2020 overlap rule, NMFS is proposing that the non-entangling FAD requirements, revised shark requirements, and fishing restrictions for mobulid rays would not apply in the overlap area, and the IMO number requirement would apply in the overlap area.

As described above, the elements of the proposed rule fall into the following four categories: (1) Non-entangling FAD requirements; (2) IMO number requirement; (3) revised purse seine restrictions for the oceanic whitetip shark and the silky shark and additional shark release requirements for all vessels; (4) and fishing restrictions for mobulid rays. Each of these elements of the proposed rule is described in more detail below.

Non-Entangling FAD Requirements

The proposed rule would implement the FAD design requirements set forth in paragraph 19 of CMM 2018–01. These provisions would be implemented in a manner that is consistent with NMFS’s implementation of the FAD design requirements in Resolution C–18–05 of the IATTC, which manages tuna purse seine fisheries in the eastern Pacific Ocean (EPO). U.S. purse seine vessels sometimes fish in the WCPO and EPO on the same fishing trip and FADs are known to drift from the EPO into the WCPO, so ensuring consistent FAD design requirements would enable NMFS to better implement and enforce both the WCPFC and IATTC decisions on FAD designs.

Under the proposed rule, if the FAD design includes a raft (*e.g.*, flat raft or rolls of material) and if mesh netting is used as part of the structure, the mesh netting shall have a stretched mesh size less than 7 cm and the mesh net must be tightly wrapped such that no netting hangs below the FAD when deployed. Additionally, any netting used in the subsurface structure of the FAD must be tightly tied into bundles (“sausages”) or have a stretched mesh size less than 7 cm in a panel that is weighted on the lower end with at least enough weight to keep the netting taut in the water column. These requirements are the same as those specified at 50 CFR 300.28(e), which implement IATTC’s

FAD design requirements for the EPO specified in Resolution C–18–05.

This element of the proposed rule would apply to all purse seine vessels used for commercial fishing for HMS on the high seas and in exclusive economic zones in the Convention Area (excluding the overlap area).

IMO Number Requirement

Existing regulations at 50 CFR 300.217(c) apply to all U.S. fishing vessels (including those participating in the fisheries of the U.S. Participating Territories) that are used for commercial fishing for highly migratory fish stocks in the Convention Area either on the high seas or in waters under the jurisdiction of a foreign nation, and the gross tonnage of which is at least 100 GRT or 100 GT (gross tons). The owner of any such fishing vessel is required to ensure that an “IMO number” has been issued for the vessel. An “IMO number,” as stated above, is the number—sometimes called an IMO ship identification number—issued for a ship or vessel under the ship identification number scheme established by the IMO. Currently, IMO numbers are issued on behalf of the IMO by Information Handling Services (IHS) Markit, the current administrator of the IMO ship identification number scheme. A vessel owner may request that an IMO number be issued by following the instructions given by IHS Markit, available at: www.imonumbers.lrfairplay.com. There is no fee for making such a request or having an IMO number issued, but specific information about the fishing vessel and its ownership and management must be provided to the administrator of the scheme. The existing regulations include a process for fishing vessel owners to request an exemption from NMFS if they are unable to obtain IMO numbers. When NMFS receives such a request it will review it and assist the fishing vessel owner as appropriate. If NMFS determines that it is infeasible or impractical for the fishing vessel owner to comply with the requirement, NMFS will issue an exemption from the requirement for a specific or indefinite amount of time. The exemption will become void if ownership of the fishing vessel changes.

Under the proposed rule, the existing regulations would be revised to include vessels less than 100 GRT down to a size of 12 meters in LOA. This element of the proposed rule would apply to vessels used for commercial fishing for HMS in the Convention Area, including the overlap area, either on the high seas or in waters under the jurisdiction of a foreign nation. NMFS has established

regulations, at 50 CFR 300.22(b)(3)(iii), which implement similar requirements for vessels used for fishing on the high seas in the EPO, as specified in IATTC Resolution C-18-06.

Revised Purse Seine Restrictions for Oceanic Whitetip Shark and Silky Shark and Additional Shark Release Requirement for All Vessels

The proposed rule would implement two specific provisions of CMM 2019-04: (1) An exemption from existing no-retention requirements for purse seine vessels in specific cases where an oceanic whitetip shark or silky shark is not seen during fishing operations and are delivered into the vessel hold; and (2) a requirement for vessels to haul any incidentally caught sharks alongside the vessel before being cut free in order to facilitate species identification.

Existing regulations under 50 CFR 300.226 prohibit the crew, operator, and owner on all vessels used for commercial fishing for HMS in the Convention Area from retaining on board, transshipping, storing, or landing any part or whole carcass of an oceanic whitetip shark or silky shark that is caught in the Convention Area, unless collected by an on-board observer. The proposed rule would establish an exemption for purse seine fishing vessels in the case of any silky shark or oceanic whitetip shark that is not seen during the fishing operation and is unknowingly delivered into the vessel hold and frozen. In such a case, under the proposed rule, oceanic whitetip shark and silky shark could be stored and landed, but the vessel owner or operator would be required to notify the observer and surrender the whole shark to the responsible government authorities or discard the shark at the first point of landing or transshipment. In U.S. ports the responsible government authority is the NOAA Office of Law Enforcement divisional office nearest to the port. Under the proposed rule, it would be prohibited to sell or barter oceanic whitetip shark and silky shark surrendered in this manner, but they could be donated for purposes of human consumption, consistent with any applicable laws and policies. NMFS has established regulations at 50 CFR 300.27(f) that implement a similar exemption for certain cases where a silky shark is caught and frozen as part of a purse seine operation in the EPO.

The proposed rule would also require that any shark be hauled alongside the vessel before being cut free (if on a line or entangled in a net) in order to facilitate species identification by the observer on board. This element of the proposed rule would only apply to

vessels on which a WCPFC observer or camera monitoring device are present on board.

Both of these shark elements of the proposed rule would apply to all U.S. vessels used for commercial fishing for HMS on the high seas and in exclusive economic zones in the Convention Area (excluding the overlap area).

Fishing Restrictions for Mobulid Rays

The proposed rule would implement the provisions of CMM 2019-05 for mobulid rays described above. The following five mobulid ray elements would be implemented under the proposed rule:

(1) Owners and operators would be prohibited from setting on a mobulid ray if the animal is sighted prior to a set;

(2) Owners and operators would be prohibited from retaining on board, transshipping, storing, or landing any part or whole carcass of a mobulid ray;

(3) Owners and operators would be required to release any mobulid ray unharmed, as soon as possible, in a manner that would result in the least possible harm to the individuals captured, taking into consideration the safety of the crew;

(4) Owners and operators would be required to allow observers to collect biological samples of mobulid rays, if requested to do so by a WCPFC observer; and

(5) An exemption for purse seine vessels from elements 1 and 2 in specific cases where a mobulid ray is not seen during fishing operations and is unknowingly delivered into the vessel hold. In such cases, a vessel owner or operator would be required to notify the observer on board, and surrender the whole mobulid ray at the first point of landing, to the responsible government authorities, or other competent authority, or discard it. It would be prohibited to sell or barter mobulid rays surrendered in this manner, but they could be donated for purposes of human consumption, consistent with any applicable laws and policies.

The five mobulid ray elements of the proposed rule would apply to U.S. vessels used for commercial fishing for HMS on the high seas and EEZs in the Convention Area (excluding the overlap area). The mobulid ray elements of the proposed rule are similar to provisions that have been adopted by the IATTC, as specified in Resolution C-15-04, and that have been implemented in the EPO at 50 CFR 300.27.

Classification

The Administrator, Pacific Islands Region, NMFS, has determined that this proposed rule is consistent with the

WCPFC Implementation Act and other applicable laws, subject to further consideration after public comment.

Coastal Zone Management Act (CZMA)

NMFS determined that this action is consistent to the maximum extent practicable with the enforceable policies of the approved coastal management program of American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, and the State of Hawaii. Determinations to Hawaii, American Samoa, CNMI and Guam were submitted on August 2, 2021, for review by the responsible state and territorial agencies under section 307 of the CZMA.

Executive Order 12866

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

Regulatory Flexibility Act (RFA)

An IRFA was prepared, as required by section 603 of the RFA. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, as well as its objectives, and the legal basis for this action are contained in the **SUMMARY** section of the preamble and in other sections of this **SUPPLEMENTARY INFORMATION** section of the preamble. The analysis follows:

Estimated Number of Small Entities Affected

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 114111) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of \$11 million for all its affiliated operations worldwide.

The proposed rule would apply to owners and operators of U.S. commercial fishing vessels used to fish for HMS in the Convention Area. This includes vessels in the purse seine, longline, tropical troll (including those in American Samoa, the CNMI, Guam, and Hawaii), Hawaii handline, Hawaii pole-and-line, and west coast-based albacore troll fleets. For the purpose of this analysis, the number of vessels registered to fish for HMS in the Convention Area in 2020 is used as an estimate for the number of future affected fishing vessels. The estimated

number of affected fishing vessels is as follows based on the number of vessels reported in the 2021 U.S. Annual Report Part 1 to WCPFC (for the 2020 fishing year): 23 purse seine vessels, 158 longline vessels, 21 albacore troll vessels, 1,742 tropical troll and handline vessels, and 2 pole-and-line vessels. Thus, the total estimated number of vessels that would be subject to the rule is 1,946.

Based on limited financial information about the affected fishing fleets, and using individual vessels as proxies for individual businesses, NMFS believes that all the affected fish harvesting businesses in all the fleets, except the purse seine fleet, are small entities as defined by the RFA; that is, they are independently owned and operated and not dominant in their fields of operation, and have annual receipts of no more than \$11.0 million. Within the purse seine fleet, analysis of revenues, by vessel, for 2018–2020 reveals that average annual per-vessel revenue was about \$9,260,000 (NMFS unpublished data on catches combined with fish price data from https://investor.thaiunion.com/raw_material.html accessed on May 6, 2021). Fifteen of the purse seine vessels active in that period had estimated average annual revenues of less than \$11 million, and thus are considered to be small entities.

Recordkeeping, Reporting, and Other Compliance Requirements

The reporting, recordkeeping and other compliance requirements of this proposed rule are described earlier in the preamble. There is one new collection-of-information associated with IMO number requirements included in this proposed action that is subject to the Paperwork Reduction Act. That collection-of-information requirement is described more fully in the Paperwork Reduction Action subsection below. The classes of small entities subject to the requirements and the costs of complying with the proposed requirements are described below to the extent possible:

Non-entangling FAD Element: To comply with this element of the proposed rule, affected vessel owners and operators would be required to use specific materials and design specifications for FADs that are deployed in, or that may drift into, the WCPFC Convention Area. This element of the proposed rule would not establish any new reporting or recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to all purse seine vessels used for commercial fishing for HMS on the high seas and in exclusive economic zones in the Convention Area (excluding the overlap area). A majority of the purse seine vessels are already subject to equivalent requirements in the EPO. NMFS has established regulations for measures adopted by the IATTC (see 83 FR 15503, April 11, 2018; 83 FR 62732, December 6, 2018), which became effective on January 1, 2019. Of the 23 purse seine vessels to which this element of the proposed rule would apply, 13 are currently active on both the WCPFC Record of Fishing Vessels (RFV) and the IATTC Regional Vessel Register (RVR), meaning that they are authorized to fish in both the WCPO and the EPO. It is expected that the owners and operators of purse seine vessels on both lists would therefore already be responsible for implementing the FAD design requirements in the EPO, as specified in 50 CFR 300.28(e). All 23³ purse seine vessels currently on the WCPFC RFV are also on the International Seafood Sustainability Foundation (ISSF) ProActive Vessel Register (PVR), and their owners and operators have agreed to comply with ISSF-adopted conservation measures, which include the use of non-entangling FADs or lower entanglement risk FADs. The ISSF lower entanglement risk FADs meet the same design specifications and material requirements in this element of the proposed rule. Therefore, for the owners and operators of all purse seine vessels that would be subject to the proposed rule, NMFS expects that there would be no change in the materials they currently use to design FADs.

To the extent that any of those vessels are not already implementing the design specifications included in the proposed rule, and for any new purse seine vessels that enter the fishery, there would likely be some costs associated with complying with this element of the proposed rule. However, it is not possible to predict the costs associated with any certainty, as FAD designs vary between vessels, and the availability of materials is expected to vary over time. If specific non-entangling FAD materials were difficult or costly to obtain (e.g., netting with 7 cm mesh size), it could affect a vessel's ability to fish on FADs. In cases where vessels choose to forego fishing on FADs, it could increase operating costs in the form of increased fuel usage to fish on unassociated

³ As of July 2021, 9 of the 23 purse seine vessels used as a baseline in this analysis are no longer flagged to the United States, and have been removed from the ISSF PVR.

schools of fish instead of fishing on FADs.

Fulfillment of these requirements is not expected to require any professional skills that the affected vessel owners and operators do not already possess.

IMO Number Element: This element of the proposed rule would require owners of fishing vessels less than 100 GRT down to a size of 12 meters LOA to obtain an IMO number. This element of the proposed rule would establish new recordkeeping requirements (within the meaning of the Paperwork Reduction Act). That collection-of-information requirement is described more fully in the Paperwork Reduction Action subsection below. The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to vessels used for commercial fishing for HMS in the Convention Area (including the overlap area), either on the high seas or in waters under the jurisdiction of a foreign nation. Existing regulations at 50 CFR 300.217(c) require that vessels at least 100 GRT obtain an IMO number, so most entities that would be required to obtain an IMO number already have them. NMFS estimates that 48 fishing vessels would initially be subject to the proposed expanded requirement, 45 longline vessels and three troll vessels. NMFS has established regulations, at 50 CFR 300.22(b)(3)(iii), which implement similar requirements for vessels fishing on the high seas in the EPO. NMFS estimates that all but one of the 48 fishing vessels initially subject to this element of the proposed rule are already subject to the IATTC IMO requirements in the EPO. NMFS projects that as fishing vessels enter the fishery in the future, roughly four per year would be required to obtain IMO numbers.

The requirement to obtain an IMO number would be a one-time requirement; once a number is issued for a vessel, the owner of the vessel would be in compliance for the remainder of the vessel's life, regardless of changes in ownership. Completing and submitting the application form (which can be done online and requires no fees) would take about 30 minutes per applicant, on average. Assuming a value of labor of approximately \$26 per hour and communication costs of about \$1 per application, the (one-time) cost to each affected entity would be about \$14. Fulfillment of these requirements is not expected to require any professional skills that the affected vessel owners and operators do not already possess.

Shark Element (1): This element of the proposed rule would provide an exemption to existing oceanic whitetip

and silky shark prohibitions in the case where an oceanic whitetip shark or silky shark is not seen during fishing operations and is unknowingly delivered into the vessel hold and frozen as part of a purse seine operation. It would not establish any new reporting and recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply specifically to U.S. purse seine vessels used for commercial fishing for HMS on the high seas or in EEZs within the Convention Area (excluding the overlap area). It is not expected that these proposed changes would cause any modification to the vessels' fishing practices, as the expectation is that they would not have seen the animal prior to delivering it into the hold. Although this element would relieve vessel owners and operators from the burden associated with the existing regulation, qualifying for the exemption could bring modest costs. If the option of discarding the animal at the first point of landing or transshipment is taken, no additional costs would be expected. If the option of surrendering the shark to the responsible government authority is taken, there could be moderate costs in terms of crew labor that may be necessary to contact the authority and surrender the shark. Under either option, the cost is would be offset by the reduced risk of monetary fines that may be associated with current regulations prohibiting the retention of oceanic whitetip sharks and silky sharks.

Fulfillment of these requirements is not expected to require any professional skills that the affected vessel owners and operators do not already possess.

Shark Element (2): This element of the rule would require that any incidentally caught shark be hauled alongside the vessel before being released in order to facilitate better species identification by the WCPFC observer on board. It would not establish any new reporting or recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to all U.S. vessels used for commercial fishing for HMS on the high seas or in EEZs within the Convention Area (excluding the overlap area); however, it would only apply to vessels on which an observer or electronic monitoring camera is present, so for the foreseeable future, it is expected that it

would apply only to purse seine and longline vessels, which currently carry observers.

For purse seine vessels, it is expected that an observer would be present on 100 percent of trips.⁴ It is expected that in most cases, the fish would be released after it is brailled from the purse seine and brought on deck. In these cases, the labor involved would probably be little different than current practice for discarded sharks. If the vessel operator and crew determined that it is possible to release the fish before it is brought on deck, it may involve greater intervention and time on the part of crew members to ensure that the observer is able to properly identify species. To the extent that time could otherwise be put to productive activities, this could lead to increased costs associated with labor.

For longline vessels, it is expected that an observer would be present on ~20 percent of trips for deep-set trips and 100 percent on shallow-set trips.⁵ In these cases, it is expected that under current fishing practices, the fish would be released as it is brought to the side of the vessel, such as by cutting the line or removing the hook. In these cases, minimal if any costs would be incurred.

This element of the proposed rule is not expected to require any professional skills that the affected vessel owners, operators and crew do not already possess.

Mobulid Ray Element (1): This element of the proposed rule would prohibit vessels from targeting mobulid rays or making a set in instances in which a mobulid ray is sighted prior to a set. This requirement would not impose any new reporting or recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to all U.S. vessels used for commercial fishing for HMS on the high seas or in the exclusive economic zones in the Convention Area (excluding the overlap area). U.S. fishing vessels in the WCPO are not known to intentionally target mobulid rays, although they are caught incidentally in both the purse seine and longline fleets and less

⁴ Due to the impacts of COVID-19, purse seine vessels have been exempted from 100 percent observer coverage requirements between March 2020 and January 2022 (see 86 FR 31178; June 11, 2021 and 86 FR 48916; September 1, 2021). This analysis assumes 100 percent observer coverage on purse seine vessels, as required under the WCPFC and the South Pacific Tuna Treaty.

⁵ Based on average percent observer coverage on Hawaii longline vessels, 2015–2019.

frequently in the tropical handline and pole-and-line fleets. It is unknown whether U.S. purse seine vessels currently intentionally set on mobulid rays. If such a practice does exist, this element of the proposed rule would be expected to impact purse seine vessels by prohibiting them from setting on a mobulid ray if sighted prior to a set.

In the event that a mobulid ray is sighted prior to a desired set, complying with the proposed rule could cause forgone fishing opportunities and result in economic losses. It is difficult to project the frequency of pre-set mobulid ray-sighting events because such events are not recorded. Historical data on mobulid ray interactions are available, but interactions are not equivalent to pre-set sightings. According to anecdotal information from purse seine vessel operators, a majority of mobulid rays are not seen before the set commences. Nonetheless, historical mobulid ray interaction rates can provide an upper bound estimate of the frequency of pre-set mobulid ray sighting events in the future. Based on unpublished observer data from the Pacific Islands Forum Fisheries Agency (FFA) observer program between 2015 and 2019, mobulid ray interactions occur in approximately 3 percent of observed purse seine sets on average in the purse seine fishery (100 percent of sets were observed in 2015–2019). In those instances where a mobulid ray is sighted prior to a set, the vessel operator would have to wait and/or move the vessel to find the next opportunity to make a set. The consequences in terms of time lost, distance travelled, and associated costs cannot be projected with any certainty, but a range of possible outcomes can be foreseen. At worst, the operator would lose the opportunity to make a set for the remainder of the day. At best, the operator would find an opportunity to make a set soon after the event—that is, on the same day, and limited costs would be incurred. This element of the proposed rule is not expected to require any professional skills that the affected vessel owners, operators and crew do not already possess.

Mobulid Ray Element (2): This element of the proposed rule would prohibit vessels from retaining on board, transshipping, or landing any mobulid ray in the Convention Area. This requirement would not impose any new reporting or recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to all U.S. vessels used for

commercial fishing for HMS on the high seas or in the EEZs in the Convention Area (excluding the overlap area). U.S. fishing vessels in the WCPO are not known to intentionally target mobulid rays, although they are caught incidentally in both the purse seine and longline fleets and less frequently in the tropical handline and pole-and-line fleets. There are no recorded interactions with mobulid rays in the tropical troll or albacore troll fleets.

Unpublished observer data from the FFA observer program and NOAA's Pacific Islands Observer program indicate that between 2015 and 2019, an estimated two mobulid rays were retained per year in the purse seine fishery, on average, and in the longline fishery, it is estimated that that less than one mobulid ray was retained per year, on average. The remainder of the mobulid catch was released alive or discarded dead. In the tropical handline and pole-and-line fleets, there were no reported mobulid rays retained between 2015 and 2019. This requirement would foreclose harvesting businesses' opportunity to retain and sell or otherwise make use of any species of mobulid ray that may previously have been retained by U.S. fishing vessels. The consequences in terms of opportunity loss cannot be projected with any certainty; however, available data indicate that there is no history of commercial sale of mobulid rays by U.S. fishing vessels. Additionally, existing requirements under 50 CFR 300.27 prohibit vessels from retaining on board, transshipping, storing, landing, or selling any part or whole carcass of a mobulid ray that is caught in the IATTC Convention Area in the EPO. For those vessels that fish in both the WCPO and EPO, it is expected that they would already be responsible for implementing the retention prohibition requirements included in the EPO.

This element of the proposed rule is not expected to require any professional skills that the affected vessel owners, operators and crew do not already possess.

Mobulid Ray Element (3): This element of the proposed rule would require vessels to release any mobulid ray caught in the Convention Area as soon as possible and in a manner that results in as little harm to the animal as possible, without compromising the safety of any persons. This requirement would not impose any new reporting or recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to all U.S. vessels used for commercial fishing for HMS on the high seas or in the EEZs in the Convention Area (excluding the overlap area). The requirement could bring costs in the form of reduced efficiency of fishing operations if vessels were required to change their release/discard practices relative to current practices.

For purse seine vessels, it is expected that in most cases, the animal would be released after it is brailled from the purse seine and brought on deck. In these cases, the labor involved would probably be little different than current practice for discarded rays. If the vessel operator and crew determined that it is possible to release the animal before it is brought on deck, this would likely involve greater intervention and time on the part of crew members, which would be costly to the extent that time could otherwise be put to productive activities.

Existing regulations under 50 CFR 300.27 require that vessels promptly release any mobulid ray caught in the IATTC Convention Area, unharmed, and as soon as it is seen in the net or on deck. As noted above, most of the purse seine vessels registered on the WCPFC RFV are also registered to fish on the IATTC RFV, and fish in both the WCPO and the EPO, so it is expected that those vessels would already be responsible for implementing the release requirements in the EPO.

For longline, tropical handline and pole-and-line vessels, it is expected that the animal would be quickly released as it is brought to the side of the vessel, such as by cutting the line or removing the hook. In these cases, minimal if any costs would be incurred.

This element of the proposed rule is not expected to require any professional skills that the affected vessel owners, operators and crew do not already possess.

Mobulid Ray Element (4): This element of the proposed rule is a limited exemption from the mobulid retention prohibition and the mobulid release requirement in that vessel owners and operators would be relieved of those requirements in those cases where a WCPFC observer collects, or requests assistance to collect, a sample of a mobulid ray, if requested to do so by a WCPFC observer. This requirement would not impose any new reporting or recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below to the extent possible.

This element of the proposed rule would apply to all U.S. vessels used for

commercial fishing for HMS on the high seas or in the EEZs in the Convention Area (excluding the overlap area). Under existing regulations, operators and crew of vessels with WCPFC Area Endorsements (*i.e.*, vessels authorized to be used for commercial fishing for HMS on the high seas in the Convention Area) are already required to assist WCPFC observers in the collection of samples. This element of the proposed rule would effectively expand that requirement—specifically for mobulid rays—to vessels not required to have WCPFC Area Endorsements. This element may bring additional costs to fishing businesses because it may require the owner, operator, and crew to assist the observer in the collection of samples if requested to do so by the observer. It is not possible to project how often observers would request assistance in collecting samples. When it does occur, it is not expected that sample collection would be so disruptive as to substantially delay or otherwise impact fishing operations, but the fishing business could bear small costs in terms of crew labor, and possibly the loss of storage space that could be used for other purposes. It is not expected to require any professional skills that the affected vessel owners, operators and crew do not already possess.

Mobulid Ray Element (5): This element of the proposed rule would provide a limited exemption to elements 1 and 2 in specific cases where a mobulid ray is not seen during fishing operations and is unknowingly delivered into the vessel hold and frozen. It would not establish any new reporting and recordkeeping requirements (within the meaning of the Paperwork Reduction Act). The costs of complying with this requirement are described below.

This element of the proposed rule would apply specifically to U.S. purse seine vessels used for commercial fishing for HMS on the high seas or in EEZs within the Convention Area (excluding the overlap area). It is not expected that these proposed changes would cause any modification to the vessels' fishing practices, as the expectation is that they would not have seen the animal prior to delivering it into the hold. Although this element would relieve vessel owners and operators from the burden associated with the existing regulation, the steps for discarding or surrendering the animal could bring modest costs. If the option of discarding the animal at the first point of landing or transshipment is taken, no additional costs would be expected. If the option of surrendering

the mobulid ray to the responsible government authority is taken, there could be moderate costs in terms of crew labor that may be necessary to contact the authority and surrender the animal. Under either option, the cost is would be offset by the reduced risk of monetary fines.

Fulfillment of these requirements is not expected to require any professional skills that the affected vessel owners and operators do not already possess.

Disproportionate Impacts

Small entities would not be disproportionately affected relative to large entities. Nor would there be disproportionate economic impacts based on home port. As indicted above, there could be disproportionate impacts according to vessel size for the IMO number requirement.

Duplicating, Overlapping, and Conflicting Federal Regulations

NMFS has not identified any Federal regulations that conflict with or duplicate the proposed regulations. NMFS has identified several Federal regulations that overlap with the proposed regulations. These include: The proposed non-entangling FAD requirements, which overlap with existing EPO regulations at 50 CFR 300.28(e); the proposed IMO number requirements, which overlap with existing EPO regulations at 50 CFR 300.22(b)(3)(iii); the proposed purse seine shark retention requirements, which overlap with existing EPO regulations at 50 CFR 300.27(f); and the proposed mobulid ray requirements, which overlap with existing EPO regulations at 50 CFR 300.27(i). The regulations for the EPO apply when vessels fish in the EPO, including the area of overlapping jurisdiction between the IATTC and the WCPFC (overlap area). Aside from the IMO number requirements, the regulations under this proposed rule would apply in the WCPO, excluding the overlap area. The changed IMO number requirements under this proposed rule would also apply in the overlap area.

Alternatives to the Proposed Rule

NMFS has not identified any significant alternatives to the proposed rule, other than the no-action alternative. Taking no action could result in lesser adverse economic impacts than the proposed action for many affected entities, but NMFS has determined that the no-action alternative would fail to accomplish the objectives of the WCPFC Implementation Act, including satisfying the obligations of the United

States as a Contracting Party to the Convention.

Paperwork Reduction Act

This proposed rule contains one collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act. The collection-of-information requirement in this proposed rule relates to the collection under Control Number 0648–0595, “Western and Central Pacific Fisheries Convention Vessel Information Family of Forms.” However, due to multiple concurrent actions for that collection, the collection-of-information requirement in this proposed rule will be assigned a temporary Control Number that will later be merged into Control Number 0648–0595. The proposed rule includes new collection-of-information requirement for the owners of certain fishing vessels to ensure that IMO numbers are issued for the vessels. This would be a one-time requirement; no renewals or updates would be required during the life of a vessel. A fishing vessel owner would request the issuance of an IMO number by submitting specific information about the vessel and its ownership and management to IHS Maritime, which issues IMO numbers on behalf of the IMO. If a fishing vessel requires an exemption, the owner must provide the required information to NMFS. Public reporting burden for a vessel to acquire an IMO number is estimated to average approximately 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at www.reginfo.gov/public/do/PRAMain.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of

information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Authority: 16 U.S.C. 6901 *et seq.*

Dated: September 30, 2021.

Samuel D. Rauch, III,
Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300 is proposed to be amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart O—Western and Central Pacific Fisheries for Highly Migratory Species

- 1. The authority citation for 50 CFR part 300, subpart O, continues to read as follows:

Authority: 16 U.S.C. 6901 *et seq.*

- 2. In § 300.217, revise paragraph (c)(2) to read as follows:

§ 300.217 Vessel identification.

* * * * *

(c) * * *

(2) The owner of a fishing vessel of the United States used for commercial fishing for HMS in the Convention Area, either on the high seas or in waters under the jurisdiction of any nation other than the United States, shall request and obtain an IMO number for the vessel if the gross tonnage of the vessel, as indicated on the vessel's current Certificate of Documentation issued under 46 CFR part 67, is at least 100 GRT or 100 GT ITC, or less than 100 GRT down to a size of 12 meters in overall length. An IMO number may be requested for a vessel by following the instructions given by the administrator of the IMO ship identification number scheme; those instructions are currently available on the website of IHS Markit at: www.imonumbers.lrfairplay.com.

* * * * *

- 3. In § 300.222, add paragraphs (bbb) through (eee) to read as follows:

§ 300.222 Prohibitions.

* * * * *

(bbb) Fail to comply with the FAD design requirements in § 300.223(b)(4).

(ccc) Fail to comply with the requirements of any exemption under § 300.226(e).

(ddd) Fail to comply with any of the restrictions, prohibitions or requirements specified in § 300.229.

(eee) Fail to comply with the handling and release requirements in § 300.230.

■ 4. In § 300.223, add paragraph (b)(4) to read as follows:

§ 300.223 Purse seine fishing restrictions.

* * * * *

(b) * * *

(4) FAD design requirements to reduce entanglements. Owners and operators of fishing vessels of the United States equipped with purse seine gear shall ensure that all FADs on board or deployed from the vessel in the Convention Area comply with the following design requirements:

(i) *Raft*. If the FAD design includes a raft (e.g., flat raft or rolls of material) and if mesh netting is used as part of the structure of the raft, the mesh netting shall have a stretched mesh size less than 7 centimeters and the mesh net must be tightly wrapped such that no netting hangs below the raft when deployed; and

(ii) *Subsurface*. Any netting used in the subsurface structure of the FAD must be tightly tied into bundles (“sausages”), or if not tightly tied into bundles, then must be made of stretched mesh size less than 7 centimeters and be configured as a panel that is weighted on the lower end with enough weight to keep the netting vertically taut in the water column.

* * * * *

■ 5. In § 300.226, revise paragraphs (a) and (b) and add paragraph (e) to read follows:

§ 300.226 Oceanic whitetip shark and silky shark.

* * * * *

(a) The owner and operator of a fishing vessel of the United States used for commercial fishing for HMS cannot retain on board, transship, store, or land any part or whole carcass of an oceanic whitetip shark (*Carcharhinus longimanus*) or silky shark (*Carcharhinus falciformis*) that is caught in the Convention Area, either on the high seas or in an exclusive economic zone, unless subject to the provisions of paragraph (c) or (e) of this section.

(b) The owner and operator of a fishing vessel of the United States used for commercial fishing for HMS must release any oceanic whitetip shark or silky shark that is caught in the Convention Area, either on the high seas or in an exclusive economic zone, as soon as possible after the shark is caught

and brought alongside the vessel, and take reasonable steps for its safe release, without compromising the safety of any persons, unless subject to the provisions of paragraph (c) or (e) of this section.

* * * * *

(e) Paragraphs (a) and (b) of this section do not apply in the event that any oceanic whitetip shark or silky shark is not seen by the crew, operator, or owner of a purse seine vessel, or any WCPFC observer on board that vessel, prior to being delivered into the vessel hold and frozen. In such a case, oceanic whitetip shark or silky shark could be stored and landed, but the vessel owner or operator must notify the on-board observer and surrender the whole shark to the responsible government authorities or discard the shark at the first point of landing or transshipment. In U.S. ports, the responsible government authority is the NOAA Office of Law Enforcement. Any oceanic whitetip shark or silky shark surrendered in this manner may not be sold or bartered, but may be donated for human consumption, consistent with any applicable laws and policies.

■ 6. Add § 300.229 to read as follows:

§ 300.229 Mobulid ray restrictions.

The requirements of this section apply in all exclusive economic zones and all areas of high seas in the Convention Area, excluding the Overlap Area. For the purpose of this section, mobulid ray is defined as any ray in the family Mobulidae, which includes manta rays and devil rays (*Mobula* spp.).

(a) The owner and operator of a fishing vessel of the United States used for commercial fishing for HMS cannot set or attempt to set on or around a mobulid ray if the animal is sighted at any time prior to the commencement of the set or the attempted set.

(b) The owner and operator of a fishing vessel of the United States used for commercial fishing for HMS cannot retain on board, transship, store, or land any part or whole carcass of a mobulid ray, unless subject to the provisions of paragraphs (d) through (f) of this section.

(c) The owner and operator of a fishing vessel of the United States used for commercial fishing for HMS must release any mobulid ray, as soon as possible, and must ensure that all reasonable steps are taken to ensure its

safe release, without compromising the safety of any persons, unless subject to the provisions of paragraphs (d) through (f) of this section.

(d) Paragraphs (b) and (c) of this section do not apply in the event that a WCPFC observer collects, or requests the assistance of the vessel crew, operator, or owner in the collection of, samples of a mobulid ray in the Convention Area.

(e) The crew, operator, and owner of a vessel must allow and assist a WCPFC observer to collect samples of a mobulid ray in the Convention Area, if requested to do so by WCPFC observer.

(f) Paragraphs (b) and (c) of this section do not apply in the event that a mobulid ray is not seen by the crew, operator, or owner of a purse seine vessel, or any WCPFC observer on board that vessel, prior to being delivered into the vessel hold and frozen. In such a case, a mobulid ray could be stored and landed, but the vessel owner or operator must notify the on-board observer and surrender the whole ray to the responsible government authorities or discard the animal at the first point of landing or transshipment. In U.S. ports, the responsible government authority is the NOAA Office of Law Enforcement. Any mobulid ray shark surrendered in this manner may not be sold or bartered, but may be donated for human consumption, consistent with any applicable laws and policies.

■ 7. Add § 300.230 to read as follows:

§ 300.230 Shark handling and release.

(a) The requirements of paragraph (b) of this section apply to all fishing vessels of the United States used for commercial fishing for HMS. The requirements apply in all exclusive economic zones and all areas of high seas in the Convention Area, excluding the Overlap Area. The requirements apply only if there is a WCPFC observer or camera monitoring device on board the fishing vessel.

(b) Prior to releasing any shark that is caught during fishing operations and not brought on board the fishing vessel, the owner and operator, without compromising the safety of any persons, shall ensure that the shark is brought alongside the vessel for identification purposes.

[FR Doc. 2021–21646 Filed 10–6–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 86, No. 192

Thursday, October 7, 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

October 4, 2021.

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

Comments regarding this information collection received by November 8, 2021 will be considered. 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.

Food Safety and Inspection Service

Title: Foodborne Illness Outbreak Surveys for the FSIS Public Health Partners.

OMB Control Number: 0583–0175.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U. S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031). These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS intends to collect information from state and territorial government partners on ways to strengthen the collaborative response to illness outbreaks associated with FSIS-regulated food products.

Need and Use of the Information: FSIS will administer a series of surveys regarding foodborne illness outbreak investigation to state and territorial government partners. The results of these surveys will help FSIS assess communication trends and prioritize outreach efforts.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 200.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 67.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–21962 Filed 10–6–21; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2015–0042]

Eligibility of the Republic of Poland To Export Poultry and Poultry Products to the United States

AGENCY: Food Safety and Inspection Service, USDA

ACTION: Notice and response to comments

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that the Republic of Poland (Poland) is eligible to export poultry products to the United States. FSIS has reviewed Poland's poultry laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the United States food safety inspection system for poultry products. Therefore, poultry products derived from poultry slaughtered and processed in certified Polish establishments are now eligible for export to the United States. All such products will be subject to reinspection at United States points-of-entry by FSIS inspectors.

Applicable: Poland's poultry products eligible for import to the United States will be added to the FSIS Import Library (<https://www.fsis.usda.gov/importlibrary>) on October 7, 2021.

FOR FURTHER INFORMATION CONTACT:

Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On April 20, 2016, FSIS published a proposed rule in the **Federal Register** (81 FR 23194) to add Poland to the list of countries in the regulations eligible to export poultry products to the United States. Between the publication of the proposed rule concerning Poland's eligibility and this **Federal Register** notice, FSIS finalized rulemaking (84 FR 65265; November 27, 2019) to remove the lists of foreign countries eligible to export meat, poultry, and egg products to the United States from its regulations and instead maintain a single list of eligible countries on FSIS' website at: <https://www.fsis.usda.gov/importlibrary>. This change allows FSIS to better provide the public with the most accurate and current information. In addition, the final rule affected FSIS' process for implementing equivalence determinations. Instead of publishing proposed and final rules in the **Federal Register**, FSIS now implements equivalence determinations through **Federal Register** notices. The criteria FSIS uses to evaluate whether a foreign country is eligible to export meat, poultry, or egg products have not

changed. FSIS continues to provide an opportunity for public comment when proposing through **Federal Register** notices to list new countries as eligible to export products to the United States or to list existing countries as eligible to export certain new products.

As explained in the 2016 proposed rule to list Poland as eligible to export poultry products to the United States (81 FR 23194, April 20, 2016), under the PPIA and implementing regulations, poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States (21 U.S.C. 466). Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry products to the United States.

Paragraph 9 CFR 381.196(a) requires that the standards of a foreign country's poultry inspection system, its legal authority for the inspection system, and the regulations implementing the system be equivalent to those of the United States.

The country's inspection program must also impose requirements equivalent to those of the United States.

Evaluation of the Polish Poultry Inspection System

On April 20, 2016, FSIS published a proposed rule to determine, based on the results of audits in 2011 and 2014, that Poland's poultry inspection system is equivalent to the United States system and, therefore, to add Poland to the list of countries eligible to export poultry products to the United States in the regulations. For more detailed information on the FSIS evaluation of the Polish poultry inspection system see the 2016 Poland proposed rule (81 FR 23194, April 20, 2016), and for the full 2011 and 2014 audit reports, go to: <https://www.fsis.usda.gov/federal-register/rules/eligibility-republic-poland-export-poultry-products-united-states>.

On August 21, 2014, FSIS published the final rule Modernization of Poultry Slaughter Inspection (79 FR 49566, August 21, 2014). The rule created regulatory changes that apply to all poultry slaughter establishments and established a new optional post-mortem inspection system, the New Poultry Inspection System (NPIS). In 2016 and 2017, Poland sent letters to FSIS outlining the changes that were made to Poland's poultry inspection system to achieve equivalence with the new U.S. regulations. These included requirements that establishments have

procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and procedures to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material throughout the entire slaughter and dressing operation. FSIS reviewed the submitted letters and additional information and determined on December 29, 2017, that Poland's poultry slaughter inspection system is equivalent to the U.S. system regarding the requirements in the final rule "Modernization of Poultry Slaughter Inspection."

Poland also is eligible to ship meat products to the United States. After the publication of the 2016 proposed rule concerning Poland's equivalence for poultry, FSIS conducted an onsite audit in September 2017 to verify the ongoing equivalence of Poland's meat inspection system. Poland's 2017 onsite audit identified a finding related to government inspection personnel in certified establishments producing meat products for export to the United States and indicated that additional information was needed before making a final conclusion about whether Poland's meat products inspection system remained equivalent to that of the United States. Consequently, in 2018 during the review of Poland's comprehensive corrective action plans to address the 2017 audit finding, Poland's General Veterinary Inspectorate (GVI), which is Poland's central competent authority (CCA) in charge of food inspection, confirmed that the same inspection arrangement was used in poultry establishments that expressed interest in exporting to the United States. FSIS was concerned that contract personnel, rather than government personnel, may have been conducting inspection. In response to this information, in 2018 and 2019, Poland submitted corrective action plans that addressed FSIS' findings and ensured that government inspectors will be performing inspection activities at all slaughter and processing establishments that are eligible to export products to the United States. FSIS conducted an onsite audit from July 15 through August 1, 2019 and concluded that Poland had satisfactorily implemented the corrective action plans that it had submitted in response to the 2017 audit. For the most recent full audit reports, go to: <https://www.fsis.usda.gov/news-events/publications/poland-foreign-audit-report>.

FSIS' Equivalence Determination

After considering the comments received on the proposed rule, discussed below, FSIS concludes that

Poland's poultry inspection system is equivalent to the United States' inspection system for poultry products. Therefore, FSIS is announcing that Poland is eligible to export poultry products to the United States (9 CFR 381.196(b)). FSIS has added Poland to its list of eligible countries to export poultry products to the United States on its website at: <http://www.fsis.usda.gov/importlibrary>.

Polish poultry products will be eligible for importation into the United States only if they are from birds slaughtered on or after the publication date of this **Federal Register** notice. Under FSIS' import regulations, the government of Poland must certify to FSIS that those establishments requesting to export poultry products to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)).

Upon publication of this **Federal Register** notice, Poland is eligible to export to the United States raw and processed poultry products derived from birds slaughtered in Poland. The eligible processing categories include: Heat Treated—Shelf Stable, Not Heat Treated—Shelf Stable, Fully Cooked—Not Shelf Stable, and Thermally Processed—Commercially Sterile. Poland would need to submit additional information for FSIS to review and may need to undergo an additional audit before FSIS would allow Poland to export other raw and processed poultry products to the United States not listed above. FSIS maintains a country-specific web page¹ on FSIS' website with a list of the process categories and the product groups Poland is eligible to export to the United States.

Although a foreign country may be listed on FSIS' website as eligible to export poultry products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States, including those of USDA's Animal and Plant Health Inspection Service (APHIS). These requirements include restrictions under 9 CFR part 94 of the APHIS regulations, which regulate the importation of poultry products from foreign countries into the United States to control the spread of specific animal diseases.

All poultry products exported to the United States from Poland will be subject to reinspection by FSIS at United States points-of-entry for, but not limited to, transportation damage, product and container defects, labeling,

¹ See: <https://www.fsis.usda.gov/inspection/import-export/import-export-library/poland>.

proper certification, general condition, and accurate count.

FSIS also will conduct other types of reinspection activities, such as physical inspection and incubation of thermally processed, commercially sterile (canned) products to ensure product safety and taking product samples for laboratory analysis to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter United States commerce. If a product does not meet United States requirements, it will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import reinspection activities can be found on the FSIS website at: <https://www.fsis.usda.gov/inspection/import-export/import-guidance>.

Finally, within one year of the publication date of this **Federal Register** notice, FSIS will conduct an on-site audit of Poland's poultry inspection system to verify ongoing equivalence. During the audit, FSIS auditors will verify that Poland's CCA has implemented its food safety inspection system as described in the Self-Reporting Tool (SRT) and supporting documentation. FSIS will audit government offices, establishments, and laboratories to verify that the CCA has implemented its inspection system as documented and verify that the country's system of controls remains equivalent to the U.S. inspection system.

Summary of Comments and Responses

FSIS received two comments in response to the proposed rule. The government of Poland supported the proposed rule and one consumer advocacy organization opposed it. The following is a brief summary of the relevant issues raised in the comments and FSIS' responses.

New Poultry Inspection System (NPIS)

Comment: A consumer advocacy group requested more information on how Poland demonstrated equivalence with the United States' regulatory requirements in the final rule "Modernization of Poultry Slaughter Inspection" (79 FR 49566, Aug. 21, 2014). Additionally, the consumer advocacy group questioned whether

Poland would implement an inspection system similar to NPIS.

Response: As stated earlier, in 2016 and 2017, Poland sent letters to FSIS outlining the changes that were made to Poland's poultry inspection system to achieve equivalence with the FSIS' new regulations. These included requirements that establishments have procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and procedures to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material throughout the entire slaughter and dressing operation. FSIS reviewed the submitted letters and additional information from Poland and determined on December 29, 2017, that Poland's poultry slaughter inspection system is equivalent to the U.S. system regarding the requirements in the final rule, "Modernization of Poultry Slaughter Inspection." Poland also explained in the letters that it does not plan to implement an inspection system like NPIS in any of its establishments. If Poland later chooses to implement NPIS, Poland will need to implement regulations for that inspection system equivalent to United States' NPIS regulations.

Audit Report Findings

Comment: The consumer advocacy organization expressed concern regarding the two audits of Poland's poultry inspection system. The organization argued that the 2011 audit revealed major issues with Poland's poultry inspection system that prevented FSIS from moving forward with rulemaking. According to the organization, the issues found in the 2014 audit are recurring problems from the 2011 audit.

Response: Poland responded to the FSIS' 2011 audit findings with comprehensive corrective action plans that addressed all of FSIS' audit findings. Consequently, FSIS conducted a follow-up initial equivalence audit in 2014 to assess the effectiveness of the implemented corrective actions. The FSIS auditors verified that Poland had effectively implemented the proffered comprehensive corrective action plan and that Poland met the equivalence criteria for all six components. The evaluation of all data collected before, during, and after the onsite audit shows that Poland's poultry inspection system is equivalent to the United States' inspection system for poultry.

Comment: The consumer advocacy organization also expressed concern regarding establishment-level findings during the second initial onsite audit. The consumer advocacy group stated

that: (1) In one of the slaughter facilities, a Polish inspector was not performing post-mortem inspection of all carcasses for pathology, food safety issues, and defects; (2) in one of the slaughter facilities, blood was accumulating on the kill floor, leading to unsanitary conditions; (3) in one of the processing facilities, exposed product came into contact with the sides of a transporting cart and the floor; and (4) in one of the establishments, Polish inspection personnel did not issue non-compliance reports for the facility's failure to maintain verification records that meet HACCP recordkeeping requirements.

Response: The FSIS auditors deemed each of the findings highlighted by the consumer advocacy organization to be isolated incidents that have been addressed and resolved. In each case, the GVI ordered immediate corrective actions to address the findings. The CCA verified that the establishments made the necessary adjustments and provided supporting documents during and after the audit exit meeting. The auditors verified that the GVI had adequately and effectively implemented its corrective action plan and addressed the audit findings with immediate corrective action and preventive measures. FSIS' evaluation of Poland's proffered corrective actions and related implementation records provided to FSIS after the exit meeting, found that all audit findings were properly addressed.

Sample Size

Comment: The consumer advocacy organization questioned why FSIS visited only two poultry slaughter and processing establishments, two poultry processing (raw and ready-to-eat) establishments, and one poultry canning facility during the 2014 audit. According to the commenter, the number of establishments the auditor visited during the 2014 audit was not sufficient to verify that Poland addressed the findings from the 2011 audit.

Response: During onsite verification audits, FSIS visits foreign sites associated with the system that provides government oversight and inspection, including the establishments interested in exporting products to the United States, government offices, and government laboratories. The purpose of the audit is to verify that the implementation of the equivalence components of the country's food safety inspection system are consistent with its design documented by the CCA in the SRT. FSIS assesses the food safety inspection system as a whole, by verifying controls and by recognizing

that any findings identified during the audit need to be considered in the context of the overall food safety inspection system. In the 2011 Poland audit, FSIS audited two processing facilities and one cold storage facility. During the 2014 audit, FSIS audited five poultry establishments, which were all the establishments intending to export product to the United States at that time. These establishments included two slaughter and processing establishments, and three processing only establishments, including the canning facility that FSIS audited in 2011. Because of the number and types of establishments audited during the 2014 audit, FSIS is confident that the number of establishments audited was sufficient to verify that Poland had addressed the findings from the 2011 audit.

Time Between Final Audit and Publication of the Proposed Rule

Comment: The consumer advocacy organization questioned the accuracy of the information presented in the proposed rule because, according to the commenter, too much time passed between the final audit and publication of the proposed rule.

Response: The time between the final audit (2014) and the proposed rule is consistent with that for other equivalence determinations since 2007. Further, FSIS intends to conduct an audit of Poland within one year of its equivalence becoming effective. FSIS will continue to conduct annual records reviews of Poland's poultry inspection system and all imported product from Poland will be reinspected once it enters the United States. Therefore, FSIS will effectively ensure Poland meets equivalence requirements on an ongoing basis.

Trade

Comment: The consumer advocacy group stated that the proposed rule was one piece of the larger Transatlantic Trade and Investment Partnership (TTIP) negotiations and that the safety of U.S. consumers was being sacrificed for expanded trade.

Response: FSIS makes determinations of equivalence by evaluating whether foreign food inspection systems attain an equivalent level of protection provided to our domestic system; FSIS determinations for Poland are documented in this **Federal Register** notice. Thus, the TTIP negotiations had no relationship to Poland's food regulatory system or this **Federal Register** notice.

Expected Costs

FSIS updated the expected costs and benefits sections of this notice to reflect more recent trade data than FSIS used for the preliminary regulatory impact analysis (81 FR 23194, April 20, 2016). Poland is the largest poultry producer within the European Union (EU). From 2006 to 2019, Poland sharply increased its poultry production and exports. According to USDA's Foreign Agricultural Service, Poland's poultry exports exceeded 1.3 million metric tons in 2019, a 12-percent increase over 2018.² In 2019, a high pathogenic avian influenza (HPAI) outbreak led to several countries imposing import bans on Polish poultry, adversely affecting Polish poultry exports in 2020. Thus, the Government of Poland is trying to "open new market opportunities, including United States market access."³

Poland's poultry production consists of 85 percent young chickens ("broilers"), 14 percent young turkey, and about one percent other poultry species such as duck and geese.^{4 5} Currently, almost 70 percent of Polish chicken meat exports go to neighboring EU markets, particularly to the United Kingdom, Germany, and France.⁶ For Poland to export poultry to the United States, it must be export-eligible, export-capable, and price-competitive. After comparing Poland's price competitiveness with the United States, Chile, and Canada, FSIS estimated that the maximum potential Polish poultry products exports to the United States is expected to be between 19,400 MT to 31,600 MT.⁷ This means, at a maximum, the total United States poultry supply will increase only between 0.10 percent and 0.16 percent (19,400 MT to 31,600 MT from Poland compared to a United

² See: USDA FAS GAIN Report: Poultry and Products Annual, Poland, March 26, 2020. Report Number PL2020-0012 Prepared by Piotr Rucinski at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=PoultryandProductsAnnual_Warsaw_Poland_03-18-2020.

³ Ibid.

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.

⁷ FSIS estimated the maximum potential Polish poultry products by identifying poultry products imported from Canada and Chile (these two countries account for more than 97% of the poultry products imported to the United States). FSIS assumed the potential volume of Polish poultry products that would be exported to the U.S. was equal to the volume of Polish poultry products that had a unit price lower than Chile's and Canada's poultry products unit prices (from 2018 and a 3-year average).

FSIS then used the volume of U.S. imports for these products (based on 2018 data and a 3-year average) to estimate the maximum potential Polish poultry exports.

States slaughter volume of 20.1 million MT in 2020)⁸, leaving the total United States poultry supply almost unchanged. Thus, Poland's poultry exports to the United States are expected to minimally change domestic poultry prices, not enough to alter the United States poultry market.

The above cost analysis is based on Poland's maximum potential poultry exports. Currently, however, 24 establishments in Poland intend to export poultry products to the United States.⁹ The total processing capacity of these 24 establishments is far less than Poland's total poultry export capacity. With minimal price changes expected in United States poultry products markets, Poland's eligibility to export poultry products to the United States should not have a negative effect on United States consumers.

Expected Benefits

The volume of trade stimulated by Poland's eligibility to export poultry products to the United States is likely to be small and is expected to have little or no effect on United States poultry supplies or poultry prices. United States consumers, however, are expected to enjoy more choices when purchasing poultry products. This equivalence determination will, therefore, expand choices for United States consumers and promote economic competition.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides

⁸ USDA, Foreign Agricultural Service, Production, Supply and Distribution. <https://apps.fas.usda.gov/psdonline/app/index.html#/app/advQuery>.

For 2020 U.S. Production, please see November 2020 WASDE Report at: <https://www.usda.gov/ocel/commodity/wasde>. The numbers have been converted to Metric Ton.

⁹ Source: Correspondence with the government of Poland.

automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 *et seq.*, the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.*, Braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) fax: (202) 690-7442;

or (3) email: program.intake@usda.gov. USDA is an equal opportunity provider, employer, and lender.

Paul Kiecker,
Administrator.

[FR Doc. 2021-21889 Filed 10-6-21; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Privacy Act of 1974; Proposed New System of Records

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice of a proposed new privacy system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, and Office of Management and Budget (OMB) Circular No. A-108, notice is given that the Food and Nutrition Service (FNS) of the U.S. Department of Agriculture (USDA) is proposing to add a new system of records, entitled USDA/FNS-12, which will replace The Integrity Profile (TIP) as the system used to house State agency vendor management data for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). This system maintains records of activities conducted pursuant to FNS' mission and responsibilities authorized by legislation.

DATES: This notice is effective upon publication, subject to a 30-day notice and comment period in which to comment on the routine uses described below. Comments, if any, must be submitted by November 8, 2021.

ADDRESSES: You may submit comments, identified by USDA/FNS-12, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov> provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Follow the online instructions at that site for submitting comments.

- *Mail:* Amy Herring, Chief, Program Integrity & Monitoring Branch, Food and Nutrition Service, Braddock Metro Center II, 1320 Braddock Place, Office 3030, Alexandria, VA 22314.

- *Email:* SM.fn.FDPHelp@usda.gov.

- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

- *Docket:* For access to the docket to read background documents or

comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For general questions please contact the FNS Privacy Officer via telephone at (703) 305-1627 or via email at SM.fn.Privacy-FNS@usda.gov.

SUPPLEMENTARY INFORMATION:

Statutory Basis

The Statutory Basis for establishing the Food Delivery Portal (FDP) is Title 7, Agriculture of the Code of Federal Regulations, Section 246.12. Section 246.12 sets forth design and operational requirements for food delivery systems; makes State agencies responsible for the fiscal management of, and accountability for, the food delivery systems under its jurisdiction; provides FNS with oversight authority over State agencies; and dictates that all contracts or agreements entered into by the State or local agency for the management or operation of food delivery systems must conform to the requirements of 2 CFR part 200, subpart D, and USDA implementing regulations 2 CFR part 400 and part 415. Food delivery systems are defined as the method by which state and local agencies provide supplemental food to program participants.

Background

The FDP will replace the current TIP system, which was developed in fiscal year (FY) 2005 and has had no major upgrades since FY 2009. Although TIP exceeds industry standards for the software development life cycle, the current data structure and reporting interface make it difficult to conduct the meaningful data analysis necessary to provide effective federal oversight of WIC.

The data collected in TIP is critical to providing effective federal oversight of the WIC Program because the information informs FNS on State agency performance regarding vendor training, compliance, monitoring, and sanctions. TIP data may also be used by State agencies to assess trends in vendor compliance and identify areas for additional training and oversight.

FDP will include functionality that will improve program oversight and integrity in all areas of WIC vendor management, as well as address gaps found in the 2013 Office of Inspector General (OIG) audit. OIG found that two of the three State agencies that OIG visited were not properly monitoring and sanctioning vendors. FDP will collect monitoring and sanctioning information to enable FNS oversight of those activities. FDP will also reduce

security risks, facilitate streamlined data collection methods, and utilize data analytics for early detection of fraudulent activities or State agency noncompliance.

Consistent with USDA's information sharing mission, information stored in FDP may be shared with other USDA components, as well as appropriate Federal, State, local, tribal, foreign, or international government agencies. This sharing will only take place after USDA determines that the receiving component or agency has a need to know the information to carry out national security, law enforcement, immigration, intelligence, or other functions consistent with the routine uses set forth in this System of Records Notice.

FDP will replace TIP as the system used to house State agency data for the WIC Program. The information housed in FDP will be critical to providing effective federal oversight because the information informs FNS on State agency performance regarding vendor training, compliance, monitoring, and sanctions. FDP will improve program oversight and integrity in vendor management as well as addressing gaps found in the 2013 OIG audit report. FDP will also reduce security risks, facilitate streamlined data collection methods, and utilize data analytics for the early detection of fraudulent activities regarding State agency noncompliance.

Privacy Act

The Privacy Act of 1974 (the Privacy Act), 5 U.S.C. 552a, embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a system of records. A system of records is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and legal permanent residents.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to which personally identifiable information is put, and to assist individuals to more

easily find such files within the agency. Below is the description of the FDP system of records.

In accordance with 5 U.S.C. 552a(r), USDA has provided a report of this new system to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

USDA/FNS-12, Food and Nutrition Service (FNS), Women, Infants, and Children (WIC) Food Delivery Portal (FDP).

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

The FDP is maintained in a cloud infrastructure environment that is used only by Federal employees and contractors and State agency employees and contractors. The data is processed and stored solely within the continental United States. Any paper records which contain PII are located in FNS Regional Offices throughout the United States. The location of each FNS Regional Office may be found in the local phone books or at <https://www.fns.usda.gov/fns-regional-offices>.

SYSTEM MANAGER(S):

Amy Herring, Chief, Program Integrity & Monitoring Branch, Food & Nutrition Service, Braddock Metro Center II, 1320 Braddock Place, STE 3030, Alexandria, VA 22314, Amy.Herring@usda.gov, (703) 305-2376.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

7 CFR 246.12.

PURPOSE(S) OF THE SYSTEM:

The purpose of FDP is to house vendor management information submitted by State agencies. The information housed in the FDP will be critical to providing effective federal oversight, because the information informs the FNS on State agency performance regarding vendor training, compliance, monitoring, and sanctions. The FDP will replace The Integrity Profile (TIP), which is the legacy system used to house State agency vendor management data for WIC Program.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include USDA employees and contractors, store owners, and State agency users.

CATEGORIES OF RECORDS IN THE SYSTEM:

The following are the Categories of Records for FDP, which are all stored within various logical objects in FDP data model. The Contact object stores:

The store's owner first and last name; system user first and last name; and an email address for each user. The FDE object stores: The store's tax identification number; the store's assigned Supplemental Nutrition Assistance Program (SNAP) number; and the store's assigned unique Salesforce ID. The Store Tracking and Redemption System (STARS) Store Data object stores: the store's tax identification number and the store's assigned SNAP number.

RECORD SOURCE CATEGORIES:

Information in this system is provided to FNS by the State agencies that administer the WIC Program at the State level. If the State agency user provides a store's assigned SNAP number, then certain data is imported from the USDA STARS system. The data imported from STARS is the store's owner name(s); store's tax identification number; and the store's assigned SNAP number.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside USDA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(1) To the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records:

(2) To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

(3) When a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule,

or order issued pursuant thereto, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative or prosecutive responsibility of the receiving entity.

(4) Disclosure to contractors under section (m): To agency contractors, grantees, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. § 552a(m).

(5) Disclosure to NARA: Records from this system of records may be disclosed to the National Archives and Records Administration (NARA) or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

(6) Information security breaches: To appropriate agencies, entities, and persons when (1) [the agency] suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(7) To WIC State agencies when a request is received, to provide back to them any information that originated from the State agency as a part of the normal usage of the system. The FDP system will be used by WIC State agencies to provide data to the agency on WIC vendor management activities. The data provided will include store's business names; store's tax identification numbers; the store's assigned SNAP number; and the store's assigned unique Salesforce ID. The

Supplemental Nutrition Assistance Program (SNAP) data disclosure to WIC State agencies: State agencies will be provided with data from the SNAP STARS system via FDP screens and reports. This data will only be provided if the WIC State agency provides an exact match of the agency number in SNAP's STARS system for a specific store. This information is provided to assist the State agency in determining program eligibility and ensuring program integrity in dually authorized stores.

(8) To another Federal agency or Federal entity, when USDA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The FDP will be hosted in a cloud infrastructure environment.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The user's permission level will dictate what records they can retrieve. Records can be retrieved by searching for the Food Delivery Entity (FDE) name, FNS Authorization Number, Federal Employer Identification Number (FEIN), or the State WIC ID (a.k.a. Vendor ID).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

FDP is a new System of Records that does not yet have a Records Schedule approved by the National Archives and Records Administration (NARA). The records within FDP will be retained indefinitely until NARA has approved a Records Schedule for FDP. The proposed Record Schedule for FDP dictates that records will be retained and disposed of in accordance with the NARA General Record Schedules (GRSs) 3.1 and 5.2. GRS 3.1 applies to system documentation whereas GRS 5.2 applies to electronic and paper inputs and outputs. Records may be retained for a longer period as required by litigation, investigation, and/or audit. Electronic and/or paper records are retained with USDA employees and contractors at USDA offices.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

USDA safeguards records in this system according to applicable rules and policies, including all applicable USDA automated systems security and access policies. USDA has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

FDP utilizes a robust collection of technical safeguards to ensure the integrity of the platform. FDP is hosted in a secure server environment that uses a firewall to prevent interference or access from outside intruders. When accessing FDP, Secure Socket Layer (SSL) technology protects the user's information by using both server authentication and data encryption. FDP administrators will have a suite of security tools that can be used to increase the security of the system. From a physical security standpoint, the servers that host FDP are stored in a privately owned data center with strict physical access control procedures in place to prevent unauthorized access.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the component's FOIA Officer, whose contact information can be found at http://www.da.usda.gov/foia_agency_pocs.htm. If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief FOIA Officer, Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 7 CFR 1.112. You must submit a written request in accordance with the instructions set forth in the system of records. The request should include the name of the individual making the request, the name of the system of records, any other information specified in the system notice, and when the request is one for access, a statement of whether the requester desires to make a personal inspection of the records or by supplied with copies by mail or email.

You must also include with your request sufficient data for FNS to verify your identity. If the sensitivity of the records warrant it, FNS may require that you submit a signed, notarized statement indicating that you are the individual to whom the records pertain and stipulating that you understand that knowingly or willfully seeking or obtaining access to records about another individual under false pretenses is a misdemeanor punishable by fine up to \$5,000. No identification shall be required, however, if the records are required by 5 U.S.C. 552 to be released. If FNS determines to grant the requested access, fees may be charged in accordance with § 1.120 before making the necessary copies. In place of a notarization, your signature may be submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their requests to the System Manager listed above. The request should identify each particular record in question, state the amendment or correction desired, and state why the individual believes that the record is not accurate, relevant, timely, or complete. The individual may submit any documentation that would be helpful. If the individual believes that the same record is in more than one system of records, the request should state that and be addressed to each component that maintains a system of records containing the record.

NOTIFICATION PROCEDURES:

See RECORD ACCESS PROCEDURES.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2021-21941 Filed 10-6-21; 8:45 am]

BILLING CODE 3410-30-P

AMERICAN BATTLE MONUMENTS COMMISSION

Performance Review Board Appointments

AGENCY: American Battle Monuments Commission.

ACTION: Notice of performance review board appointments.

SUMMARY: This notice provides the names of individuals who have been appointed to serve as members of the

American Battle Monuments Commission Performance Review Board. The publication of these appointments is required by the Civil Service Reform Act of 1978.

DATES: These appointments are effective as of 01 October 2021.

FOR FURTHER INFORMATION CONTACT:

Jamilyn Smyser, Chief of Human Resources and Administration, American Battle Monuments Commission, Courthouse Plaza II Suite 500, 2300 Clarendon Boulevard, Arlington, Virginia 22201. Telephone number: (703) 584-1544.

American Battle Monument Commission SES Performance Review Board—2020/2021

Dr. Erin Mahan, Chief Historian, Office of the Secretary of Defense
Mr. Mark Averill, Deputy Administrative Assistant to the Secretary of the Army
Michael Conley, Chief of Staff, American Battle Monuments Commission

Jamilyn Smyser,

Chief, Human Resources and Administration.

[FR Doc. 2021-21882 Filed 10-6-21; 8:45 am]

BILLING CODE 6120-01-P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

DATES: Thursday, October 21, 2021, 12:00 p.m. ET.

ADDRESSES: Virtual Briefing via Commission <https://www.youtube.com/user/USCCR/videos>.

FOR FURTHER INFORMATION CONTACT:

Angelia Rorison: 202-376-7700; publicaffairs@usccr.gov.

SUPPLEMENTARY INFORMATION: On Thursday, October 21, 2021, at 12 p.m. Eastern Time, the U.S. Commission on Civil Rights will hold a virtual briefing on the civil rights implications of the federal response and impact of Hurricane Harvey in Texas. At this virtual public briefing, the Commissioners will hear from subject matter experts such as government officials, volunteer organizations, non-governmental advocates, and academics. The Commission will accept written materials from the public for consideration as we prepare our report; submit to harveybriefing@usccr.gov no later than November 22, 2021.

This briefing is open to the public via livestream on the Commission's

YouTube Page at <https://www.youtube.com/user/USCCR/videos>. (Streaming information subject to change.) Public participation is available for the event with view access, along with an audio option for listening. Written testimony and other materials can be found on the Commission's www.usccr.gov.

Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Thursday, October 21, 2021, is <https://www.streamtext.net/player?event=USCCR>. Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

To request additional accommodations, persons with disabilities should email access@usccr.gov by Monday, October 11, 2021, indicating "accommodations" in the subject line.

Agenda for Civil Rights Implications of Disaster Relief: Hurricane Harvey in Texas: 12:00 p.m.–2:55 p.m. All Times Eastern

I. Introductory Remarks by Chair Norma V. Cantú: 12:00–12:05 p.m.

II. Remarks by Commissioner Debo Adegbile and Michael Yaki: 12:06–12:10 p.m.

III. Panel 1: 12:11–1:25 p.m.

IV. Break: 1:25–1:35 p.m.

V. Panel 2: 1:35–2:50 p.m.

VI. Closing Remarks by Chair Norma V. Cantú: 2:50–2:55 p.m.

VI. Adjourn Meeting.

** Public Comments will be accepted through written testimony only.

* Schedule is subject to change.

Call for Public Comments

In addition to the testimony collected on Thursday, October 21, 2021, via virtual briefing, the Commission welcomes the submission of material for consideration as we prepare our report. Please submit such information to harveybriefing@usccr.gov no later than November 22, 2021, or by mail to OCRE/ Public Comments, ATTN: Harvey Briefing, U.S. Commission on Civil Rights, 1331 Pennsylvania Ave. NW, Suite 1150, Washington, DC 20425. The Commission encourages the use of email to provide public comments due to the current COVID-19 pandemic.

Dated: October 5, 2021.

Angelia Rorison,

Media and Communications Director, U.S. Commission on Civil Rights.

[FR Doc. 2021-22063 Filed 10-5-21; 4:15 pm]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS**Notice of Public Meeting of the Minnesota Advisory Committee to the U.S. Commission on Civil Rights**

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Minnesota Advisory Committee (Committee) to the U.S. Commission on Civil Rights will convene by video conferencing system, WebEx, at 12:00 p.m. Central Time on Tuesday, October 19, 2021.

DATES: The meeting will take place at 12:00 p.m. Central Time on Tuesday, October 19, 2021.

PUBLIC WEBEX CONFERENCE LINK (Audio/Visual):

<https://civilrights.webex.com/civilrights/j.php?MTID=mab2de971c395b4b3ca13ba265188a39a>.

TELEPHONE (Audio Only): Dial 800-360-9505 USA Toll Free; Access code: 2763 2504 738.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at dbarreras@usccr.gov or (202) 499-4066.

SUPPLEMENTARY INFORMATION:

Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email dbarreras@usccr.gov at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at lschiller@usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

Agenda

- I. Roll Call
- II. Discussion
- III. Next Steps
- IV. Open Comment
- V. Adjourn

Dated: October 1, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021-21873 Filed 10-6-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE**International Trade Administration**

[A-552-817]

Certain Oil Country Tubular Goods From the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review; 2019-2020

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain oil country tubular goods (OCTG) from the Socialist Republic of Vietnam were sold in the United States at less than normal value (NV) during the period of review (POR) September 1, 2019 through August 31, 2020.

Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 7, 2021.

FOR FURTHER INFORMATION CONTACT: Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2924.

SUPPLEMENTARY INFORMATION:**Background**

On October 30, 2020, Commerce initiated an administrative review of the antidumping duty order on OCTG from

Vietnam.¹ The review covers SeAH Steel VINA Corporation (SeAH VINA) and its U.S. affiliate Pusan Pipe America, Inc. (Pusan Pipe) (collectively, SSV).² On May 27, 2021, Commerce extended the deadline for these preliminary results by 120 days, to September 30, 2021, in accordance with section 751 (a)(3)(A) of the Act, and 19 CFR 351.213(h)(2).³

For a full description of events that have occurred since the *Initiation Notice*, see the Preliminary Decision Memorandum.⁴ A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>.

Scope of the Order

The merchandise covered by the order is certain OCTG. For a complete description of the scope of the *Order*, see the Preliminary Decision Memorandum.

Methodology

Commerce conducted this review in accordance with sections 751(a)(1)(B) and 751(a)(2)(A) of the Tariff Act of 1930, as amended (the Act). Constructed export prices have been calculated in accordance with section 772(b) of the Act. Because Vietnam is a non-market economy (NME) within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum.

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 85 FR 68840 (October 30, 2020) (*Initiation Notice*).

² Pusan Pipe is the importer of record for all of SeAH VINA's shipments of subject merchandise to the United States during the POR. See SSV's Letter, "Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from Vietnam—Response to the Department's November 4 Questionnaire," dated December 4, 2020 at 1.

³ See Memorandum, "Oil Country Tubular Goods from the Socialist Republic of Vietnam: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated May 27, 2021.

⁴ See Memorandum, "Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Vietnam-Wide Entity

Commerce's policy regarding conditional review of the Vietnam-wide entity applies to this administrative review.⁵ Under this policy, the Vietnam-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the Vietnam-wide entity in this review, the entity is not under review and the entity's rate (*i.e.*, 111.47 percent)⁶ is not subject to change.

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period September 1, 2019, through August 31, 2020:

Exporter	Weighted-average margin (percent)
SeAH Steel VINA Corporation ⁷	4.67

Disclosure, Public Comment and Opportunity To Request a Hearing

Commerce will disclose the calculations used in our analysis to parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs within 30 days after the date of publication of these preliminary results of review in the **Federal Register**.⁸ Rebuttals to case briefs, which must be limited to issues raised in the case briefs, may be filed within seven days

⁵ See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013).

⁶ See *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value*, 79 FR 53691 (September 10, 2014); see also *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Notice of Correction to the Antidumping Duty Orders with Respect to Turkey and the Socialist Republic of Vietnam*, 79 FR 59740 (October 3, 2014).

⁷ Commerce initiated a review of both SeAH VINA and Pusan Pipe, but the record shows that Pusan Pipe is a U.S. importer of OCTG that is affiliated with SeAH VINA and does not produce OCTG. See SSV's Letter, "Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from Vietnam—Response to the Department's November 4 Questionnaire," dated December 4, 2020 at 1. Therefore, we have not calculated a rate for Pusan Pipe.

⁸ See 19 CFR 351.309(c)(1)(ii).

after the time limit for filing case briefs.⁹ Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are requested to submit with each argument: (a) A statement of the issue, (b) a brief summary of the argument, and (c) a table of authorities.¹⁰ Parties submitting briefs should do so pursuant to Commerce's electronic filing system, ACCESS.¹¹ Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information.¹²

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice. Requests should contain the party's name, address and telephone number, the number of participants, whether any participant is a foreign national and a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.¹³ Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.¹⁴ Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a

statutory injunction has expired (*i.e.*, within 90 days of publication).

For assessment purposes, Commerce applied the assessment rate calculation method adopted in *Antidumping Final Modification*.¹⁵ For any individually examined respondent whose weighted average dumping margin is above *de minimis* (*i.e.*, 0.50 percent) in the final results of this review, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of sales, in accordance with 19 CFR 351.212(b)(1). Where an importer- (or customer-) specific *ad valorem* rate is greater than *de minimis*, Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.¹⁶ Where either a respondent's weighted average dumping margin is zero or *de minimis*, or an importer- (or customer-) specific *ad valorem* is zero or *de minimis*, Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.¹⁷

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For the companies listed above that have a separate rate, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis*, then zero cash deposit will be required); (2) for previously examined Vietnamese and non-Vietnamese exporters not listed above that at the time of entry are eligible for a separate rate based on a prior completed segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific cash deposit rate; (3) for all Vietnamese exporters of subject merchandise that have not been found to be entitled to a separate rate at the time of entry, the cash deposit rate will be that for the Vietnamese-wide entity; and (4) for all non-Vietnamese exporters of subject merchandise that at the time of entry are

⁹ See 19 CFR 351.309(d)(1)–(2).

¹⁰ See 19 CFR 351.309(c)(2), (d)(2).

¹¹ See 19 CFR 351.303 (for general filing requirements).

¹² See *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19*, 85 FR 41363 (July 10, 2020).

¹³ See 19 CFR 351.310(d).

¹⁴ See 19 CFR 351.212(b).

¹⁵ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012) (*Antidumping Final Modification*) described in more detail in the Preliminary Decision Memorandum.

¹⁶ See 19 CFR 351.212(b)(1).

¹⁷ See 19 CFR 351.106(c)(2).

not eligible for a separate rate, the cash deposit rate will be the rate applicable to the Vietnamese exporter that supplied that non-Vietnamese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: September 30, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—October 28, 2021 List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

[FR Doc. 2021-21901 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-890]

Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2020

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

SUMMARY: In response to requests from interested parties, the Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty (AD) order on wooden bedroom furniture (WBF) from the People's Republic of China (China) covering the period of review (POR) January 1, 2020, through December 31,

2020. Commerce has preliminarily determined that the sole mandatory respondent, Hui Zhou Tian Mei Investment Co., Ltd. (aka Hui Zhou Tian Mei Furniture Co., Ltd.) (Tian Mei), is not eligible for a separate rate and is part of the China-wide entity. Commerce is also rescinding this review with respect to all companies under review, except Tian Mei, because all requests to review these companies have been timely withdrawn. We invite interested parties to comment on these preliminary results of review.

DATES: Applicable October 7, 2021.

FOR FURTHER INFORMATION CONTACT: Krishna Hill, 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) 482-4037.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2021, Commerce initiated an administrative review of the AD order on WBF from China.¹ With the exception of Amini Innovation Corp., which requested a review of Tian Mei, all other parties timely withdrew their review requests in their entirety.² On July 8, 2021, we issued an AD questionnaire to Tian Mei.³ On July 29, 2021, Tian Mei explained that “it cannot adequately provide {Commerce} with the information it has requested.”⁴

Scope of the Order

The product covered by the *Order* is wooden bedroom furniture, subject to certain exceptions.⁵ Imports of subject merchandise are classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9403.50.9042, 9403.50.9045, 9403.50.9080, 9403.90.7005,

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 86 FR 12599 (March 4, 2021) (*Initiation Notice*).

² See American Furniture Manufacturers Committee for Legal Trade and Vaughan-Bassett Furniture Company, Inc.'s Letter, “Wooden Bedroom Furniture from the People's Republic of China: Withdrawal Of Request For Administrative Review,” dated May 25, 2021; see also Guangzhou Maria Yee Furnishings Ltd., PYLA HK LIMITED, and MARIA YEE, INC.'s Letter, “Wooden Bedroom Furniture from the People's Republic of China; Maria Yee's Withdrawal of Request for Review,” dated May 26, 2021.

³ See Commerce's Letter, AD Questionnaire, dated July 8, 2021.

⁴ See Tian Mei's Letter, “Wooden Bedroom Furniture from the People's Republic of China: Response to the Department's July 8, 2021 Questionnaire,” dated July 29, 2021.

⁵ See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China*, 70 FR 329 (January 4, 2005) (*Order*).

9403.90.7080, 9403.50.9041, 9403.60.8081, 9403.20.0018, 9403.90.8041, 7009.92.1000 or 7009.92.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.⁶

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213.

Separate Rate

In the *Initiation Notice*, we informed parties that all firms for which a NME review was initiated that wished to qualify for separate rate status must complete, as appropriate, either a separate rate application or a separate rate certification.⁷ We also informed parties that firms that submitted a separate rate application or a separate rate certification that are subsequently selected as mandatory respondents, would not be eligible for separate rate status unless they responded to all parts of the AD questionnaire that Commerce issued to them as mandatory respondents.⁸ After Tian Mei submitted a separate rate application, Commerce selected Tian Mei as the sole mandatory respondent in this review. As noted above, Tian Mei did not respond to Commerce's AD questionnaire. Consistent with Commerce's practice in such situations, as described in the *Initiation Notice*, and because Tian Mei ceased responding to Commerce's requests for information, Commerce has preliminarily determined that Tian Mei did not establish its eligibility for separate rate status, and is part of the China-wide entity.

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.⁹ Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the

⁶ For a complete description of the scope of the *Order*, see *Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018*, 85 FR 7731 (February 11, 2020) and Memorandum, “Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Wooden Bedroom Furniture from the People's Republic of China,” dated October 2, 2019.

⁷ See *Initiation Notice*, 86 FR at 12600.

⁸ *Id.* at 12601.

⁹ See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013).

entity. Because no party requested a review of the China-wide entity, the entity is not under review and the weighted-average dumping margin assigned to the China-wide entity is not subject to change as a result of this review.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party that requested a review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review in the **Federal Register**. All review requests, except the request to review Tian Mei, were timely withdrawn. Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the AD order on wooden bedroom furniture from China with respect to all of the companies/company groupings listed in the appendix to this notice.

Public Comment

Interested parties are invited to comment on these preliminary results of review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the deadline for filing case briefs. Parties who submit case or rebuttal briefs are requested to submit with each brief: (1) A statement of the issues, (2) a brief summary of the arguments, and (3) a table of authorities.¹⁰ Executive summaries should be limited to five pages total, including footnotes.¹¹ All submissions, with limited exceptions, must be filed electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).¹² Electronically filed documents must be successfully received in their entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time (ET) on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.¹³

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the

case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice in the **Federal Register**. Requests for a hearing should contain: (1) The requesting party's name, address, and telephone number; (2) the number of individuals associated with the requesting party that will attend the hearing and whether any of those individuals is a foreign national; and (3) a list of the issues the party intends to discuss at the hearing. Oral arguments at the hearing will be limited to issues raised in the case and rebuttal briefs. If a request for a hearing is made, Commerce will announce the date and time of the hearing. Parties should confirm by telephone the date and time of the hearing two days before the scheduled hearing date.

Unless otherwise extended, Commerce intends to issue the final results of this review, which will include the results of its analysis of issues raised in any case and rebuttal briefs, no later than 120 days after the date these preliminary results of review are published in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of this review, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review. If we do not alter these preliminary results of review, we intend to instruct CBP to liquidate entries of subject merchandise exported by Tian Mei, which preliminarily did not qualify for separate rate status, at the China-wide rate.

Commerce intends to issue assessment instructions regarding Tian Mei to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Commerce intends to issue assessment instructions regarding the companies for which it rescinded this review no earlier than 35 days after the date of publication of this notice in the **Federal Register**. Commerce will instruct CBP to liquidate entries of subject merchandise exported by the companies for which we rescinded the

review at the cash deposit rate required at the time of entry.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review in the **Federal Register** for all shipments of WBF from China entered, or withdrawn from warehouse, for consumption on or after the date of publication of the notice of the final results of this administrative review in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed China and non-China exporters that have a separate rate, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (2) for all China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be the rate China-wide entity rate (*i.e.*, 216.01 percent); and (3) for all non-China exporters of subject merchandise that do not have their own rate, the cash deposit rate will be the rate applicable to the China exporter(s) that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: October 1, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

Companies/Company Groupings for Which the Administrative Review Is Being Rescinded

1. Dongguan Chengcheng Group Co., Ltd.
2. Dongguan Sunrise Furniture Co.
3. Dongguan Sunrise Furniture Co., Ltd.
4. Eurosa (Kunshan) Co., Ltd.
5. Eurosa Furniture Co., (PTE) Ltd.

¹⁰ See 19 CFR 351.309(c)(2) and (d)(2).

¹¹ *Id.*

¹² See 19 CFR 351.303.

¹³ See *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19: Extension of Effective Period*, 85 FR 41363 (July 10, 2020).

6. Fairmont Designs
 7. Fortune Glory Industrial Ltd. (H.K. Ltd.)
 8. Fortune Glory Industrial, Ltd. (HK Ltd.)
 9. Golden Lion International Trading Ltd.
 10. Golden Well International (HK), Ltd.
 11. Guangzhou Maria Yee Furnishings Ltd.
 12. Hang Hai Woodcraft's Art Factory
 13. Jiangmen Kinwai Furniture Decoration Co., Ltd.
 14. Jiangmen Kinwai International Furniture Co., Ltd.
 15. Jiangsu Xiangsheng Bedtime Furniture Co., Ltd.
 16. Jiangsu Yuexing Furniture Group Co., Ltd.
 17. Lianjiang Zongyu Art Products Co., Ltd.
 18. Maria Yee, Inc.
 19. Meizhou Sunrise Furniture Co., Ltd.
 20. Nanhai Jiantai Woodwork Co. Ltd.
 21. Nathan International Ltd., Nathan Rattan Factory
 22. Perfect Line Furniture Co., Ltd.
 23. PuTian JingGong Furniture Co., Ltd.
 24. Pyla HK Ltd.
 25. Shanghai Sunrise Furniture Co., Ltd.
 26. Shenyang Shining Dongxing Furniture Co., Ltd.
 27. Shenzhen Forest Furniture Co., Ltd.
 28. Shenzhen Jiafa High Grade Furniture Co., Ltd.
 29. Shenzhen New Fudu Furniture Co., Ltd.
 30. Shenzhen Wonderful Furniture Co., Ltd.
 31. Shin Feng Furniture Co., Ltd.
 32. Stupendous International Co., Ltd.
 33. Sun Fung Co.
 34. Sun Fung Wooden Factory
 35. Sunforce Furniture (Hui-Yang) Co., Ltd.
 36. Superwood Co. Ltd.
 37. Taicang Fairmont Designs Furniture Co., Ltd.
 38. Taicang Sunrise Wood Industry Co., Ltd.
 39. Taicang Sunrise Wood Industry, Co., Ltd.
 40. Tradewinds Furniture Ltd. (successor-in-interest to Nanhai Jiantai Woodwork Co.)
 41. Wuxi Yushea Furniture Co., Ltd.
 42. Xiamen Yongquan Sci-Tech Development Co., Ltd.
 43. Yeh Brothers World Trade Inc.
 44. Yihua Lifestyle Technology Co., Ltd.
 45. Yihua Timber Industry Co., Ltd. (a.k.a. Guangdong Yihua Timber Industry Co., Ltd.)
 46. Zhangjiagang Daye Hotel Furniture Co. Ltd.
 47. Zhangzhou Guohui Industrial & Trade Co. Ltd.
 48. Zhangzhou XYM Furniture Product Co., Ltd.
 49. Zhejiang Tianyi Scientific & Educational Equipment Co., Ltd.
 50. Zhongshan Fookyik Furniture Co., Ltd.
 51. Zhongshan Golden King Furniture Industrial Co., Ltd.
 52. Zhoushan For-Strong Wood Co., Ltd.
- [FR Doc. 2021-21959 Filed 10-6-21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

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

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping duty (AD) and countervailing duty (CVD) orders and findings with August anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable October 7, 2021.

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

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various AD and CVD orders and findings with August anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at <https://access.trade.gov>, in accordance with 19 CFR 351.303.¹ Such submissions are subject to verification, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual

examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted within seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments within five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act, the following guidelines regarding collapsing of companies for purposes of respondent selection will apply. In general, Commerce has found that determinations concerning whether particular companies should be "collapsed" (e.g., treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (e.g., investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general, each company must report volume and value

¹ See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011).

data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

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

Deadline for Particular Market Situation Allegation

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

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new

factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce’s policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce’s website at <https://enforcement.trade.gov/nme/nme-sep-rate.html> on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the “Instructions for Filing the Certification” in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register**

notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding³ should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,⁴ should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on Commerce’s website at <https://enforcement.trade.gov/nme/nme-sep-rate.html> on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Application, refer to the instructions contained in the application. Separate Rate Applications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

Exporters and producers must file a timely Separate Rate Application or Certification if they want to be considered for respondent selection. Furthermore, exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following AD and CVD orders and findings. We intend to issue the final results of these reviews not later than August 31, 2022.

² See Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

³ Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any

currently incomplete segment of the proceeding (e.g., an ongoing administrative review, new shipper review, etc.) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

⁴ Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
AD Proceedings	
INDIA: Finished Carbon Steel Flanges, A-533-871	8/1/20-7/31/21
Adinath International	
Allena Group	
Alloyed Steel	
Balkrishna Steel Forge Pvt. Ltd.	
Bansidhar Chiranjilal	
Bebitz Flanges Works Private Limited	
C. D. Industries	
Cetus Engineering Private Limited	
CHW Forge	
CHW Forge Pvt. Ltd.	
Citizen Metal Depot	
Corum Flange	
DN Forge Industries	
Echjay Forgings Limited	
Falcon Valves and Flanges Private Limited	
Heubach International	
Hindon Forge Pvt. Ltd.	
Jai Auto Pvt. Ltd.	
Kinnari Steel Corporation	
Mascot Metal Manufacturers	
M F Rings and Bearing Races Ltd.	
Munish Forge Private Limited	
Norma (India) Limited	
OM Exports	
Punjab Steel Works	
Raaj Sagar Steels	
Ravi Ratan Metal Industries	
R. D. Forge	
R.N. Gupta & Co. Ltd.	
Rolex Fittings India Pvt. Ltd.	
Rollwell Forge Engineering Components and Flanges	
Rollwell Forge Pvt. Ltd.	
SHM (ShinHeung Machinery)	
Siddhagiri Metal & Tubes	
Sizer India	
Steel Shape India	
Sudhir Forgings Pvt. Ltd.	
Tirupati Forge Pvt. Ltd.	
Uma Shanker Khandelwal & Co.	
UmaShanker Khandelwal and Co.	
Umashanker Khandelwal Forging Limited	
USK Export Private Limited	
INDONESIA: Utility Scale Wind Towers, A-560-833	2/14/20-7/31/21
PT Kenertec Power System	
MALAYSIA: Polyethylene Retail Carrier Bags, A-557-813	8/1/20-7/31/21
Euro SME Sdn Bhd	
MEXICO: Light-Walled Rectangular Pipe and Tube, A-201-836	8/1/20-7/31/21
Aceros Cuatro Caminos S.A. de C.V.	
Arco Metal S.A. de C.V.	
Fabricaciones y Servicios de Mexico	
Galvak, S.A. de C.V.	
Grupo Estructuras y Perfiles	
Industrias Monterrey S.A. de C.V.	
Internacional de Aceros, S.A. de C.V.	
Maquilacero S.A. de C.V.	
Nacional de Acero S.A. de C.V.	
PEASA-Productos Especializados de Acero	
Perfiles LM, S.A. de C.V.	
Productos Laminados de Monterrey S.A. de C.V.	
Regiomontana de Perfiles y Tubos S.A. de C.V.	
Regiomontana de Perfiles y Tubos S. de R.L. de C.V.	
Talleres Acero Rey S.A. de C.V.	
Ternium Mexico S.A. de C.V.	
Tuberias Aspe S.A. de C.V.	
Tuberia Laguna, S.A. de C.V.	
Tuberias y Derivados S.A. de C.V.	
Tecnicas de Fluidos S.A. de C.V.	
REPUBLIC OF KOREA: Large Power Transformers, A-580-867	8/1/20-7/31/21
Iljin Electric Co., Ltd.	
Hyosung Heavy Industries Corporation	
Hyundai Electric & Energy Systems Co., Ltd.	

	Period to be reviewed
ILJIN LSIS Co., Ltd.	
REPUBLIC OF KOREA: Low Melt Polyester Staple Fiber, A-580-895	8/1/20-7/31/21
Toray Advanced Materials Korea, Inc.	
REPUBLIC OF KOREA: Utility Scale Wind Towers, A-580-902	2/14/20-7/31/21
CS Wind Corporation	
Dongkuk S&C Co., Ltd.	
SPAIN: Ripe Olives, A-469-817	8/1/20-7/31/21
Aceitunas Guadalquivir, S.L.	
Aceitunas Torrent, S.L.	
Agro Sevilla Aceitunas, S.Coop. (And.)/Agro Sevilla Aceitunas S.COOP Andalusia	
Alimentary Group Dcoop S. Coop. And.	
Angel Camacho Alimentacion S.L.	
SOCIALIST REPUBLIC OF VIETNAM: Frozen Fish Fillets, A-552-801	8/1/20-7/31/21
An Chau Co., Ltd.	
An Giang Agriculture and Food Import-Export Joint Stock Company (also known as Aflix or An Giang Agriculture and Foods Import-Export Joint Stock Company)	
An My Fish Joint Stock Company (also known as Anmyfish or Anmyfishco)	
An Phat Import-Export Seafood Co., Ltd. (also known as An Phat Seafood Co. Ltd. or An Phat Seafood, Co., Ltd.)	
An Phu Seafood Corp. (also known as ASEAFood or An Phu Seafood Corp.)	
Anchor Seafood Corp.	
Anvifish Joint Stock Company (also known as Anvifish, Anvifish JSC, or Anvifish Co., Ltd.)	
Asia Commerce Fisheries Joint Stock Company (also known as Acomfish JSC or Acomfish)	
Basa Joint Stock Company (also known as BASACO)	
Ben Tre Aquaproduct Import and Export Joint Stock Company (Bentre Aquaproduct)	
Bentre Forestry and Aquaproduct Import Export Joint Stock Company (Bentre Forestry and Aquaproduct Import and Export Joint Stock Company)	
Bien Dong Hau Giang Seafood Joint Stock Company (also known as Bien Dong HG or Bien Dong Hau Giang Seafood Joint Stock Co.)	
Bien Dong Seafood Company Ltd. (also known as Bien Dong, Bien Dong Seafood, Bien Dong Seafood Co., Ltd., Biendong Seafood Co., Ltd., or Bien Dong Seafood Limited Liability Company)	
Binh An Seafood Joint Stock Company (also known as Binh An or Binh An Seafood Joint Stock Co.)	
Binh Dinh Import Export Company (also known as Binh Dinh Import Export Joint Stock Company, or Binh Dinh)	
C.P. Vietnam Corporation	
Cadovimex II Seafood Import-Export and Processing Joint Stock Company (also known as Cadovimex II, Cadovimex II Seafood Import Export and Processing Joint Stock Company, or Cadovimex II Seafood Import-Export)	
CAFATEX Corporation (also known as Cafatex)	
Can Tho Animal Fishery Products Processing Export Enterprise	
Cantho Import-Export Seafood Joint Stock Company (also known as CASEAMEX, Cantho Import Export Seafood Joint Stock Company, Cantho Import-Export Joint Stock Company, Can Tho Import Export Seafood Joint Stock Company, Can Tho Import-Export Seafood Joint Stock Company, or Can Tho Import-Export Joint Stock Company)	
Cavina Seafood Joint Stock Company (also known as Cavina Fish)	
Colorado Boxed Beef Company (also known as CBBC)	
Coral Triangle Processors (dba Mowi Vietnam Co., Limited (Dong Nai))	
Cuu Long Fish Import-Export Corporation (also known as CL Panga Fish)	
Cuu Long Fish Joint Stock Company (also known as CL-Fish, CL-FISH CORP, or Cuu Long Fish Joint Stock Company)	
Da Nang Seaproducts Import-Export Corporation (also known as SEADANANG, Da Nang or Da Nang Seaproducts Import/Export Corp.)	
Dai Thanh Seafoods Company Limited (also known as DATHACO, Dai Thanh Seafoods or Dai Thanh Seafoods Co., Ltd.)	
East Sea Seafoods LLC (also known as East Sea Seafoods Limited Liability Company, ESS LLC, ESS, ESS JVC, or East Sea Seafoods Joint Venture Co., Ltd.)	
Fatifish Company Limited (also known as FATIFISH or FATIFISHCO)	
GF Seafood Corp.	
Go Dang An Hiep One Member Limited Company	
Go Dang Ben Tre One Member Limited Liability Company	
GODACO Seafood Joint Stock Company (also known as GODACO, GODACO Seafood, GODACO SEAFOOD, GODACO_SEAFOOD, or GODACO Seafood J.S.C.)	
Golden Quality Seafood Corporation (also known as Golden Quality, GoldenQuality, GOLDENQUALITY, or GoldenQuality Seafood Corporation)	
Green Farms Seafood Joint Stock Company (also known as Green Farms, Green Farms Seafood JSC, GreenFarm SeaFoods Joint Stock Company, or Green Farms Seafoods Joint Stock Company)	
GreenFeed Vietnam Corporation	
Hai Huong Seafood Joint Stock Company (also known as HHFish, HH Fish, or Hai Huong Seafood)	
Hai Thuan Nam Co Ltd.	
Hiep Thanh Seafood Joint Stock Company (also known as Hiep Thanh or Hiep Thanh Seafood Joint Stock Co.)	
Hoa Phat Seafood Import-Export and Processing J.S.C. (also known as HOPAFISH, Hoa Phat Seafood Import-Export and Processing Joint Stock Company, Hoa Phat Seafood Import-Export and Processing JSC)	
Hoang Long Seafood Processing Company Limited (also known as HLS, Hoang Long, Hoang Long Seafood, HoangLong Seafood, or Hoang Long Seafood Processing Co., Ltd.)	

	Period to be reviewed
<p>Hung Vuong Group⁵ Hung Vuong Joint Stock Company Hung Vuong Seafood Joint Stock Company Hung Vuong-Mien Tay Aquaculture Corporation (HVMT or Hung Vuong Mien Tay Aquaculture Joint Stock Company) International Development & Investment Corporation (also known as IDI or International Development and Investment Corporation, International Development & Investment Corporation or IDI International Development & Investment Corporation) Indian Ocean One Member Company Limited (also known as Indian Ocean Co., Ltd.) Lian Heng Investment Co. Ltd. (also known as Lian Heng or Lian Heng Investment) Lian Heng Trading Co. Ltd. (also known as Lian Heng or Lian Heng Trading) Nam Phuong Seafood Co., Ltd. (also known as Nam Phuong, NAFISHCO, Nam Phuong Seafood, or Nam Phuong Seafood Company Ltd.) Nam Viet Corporation (also known as NAVICO) New Food Import, Inc. Ngoc Ha Co. Ltd. Food Processing and Trading (also known as Ngoc Ha or Ngoc Ha Co., Ltd. Foods Processing and Trading) Nguyen Tran Seafood Company (also known as Nguyen Tran J-S Co) Nha Trang Seafoods, Inc. (also known as Nha Trang Seafoods, Nha Trang Seafoods-F89, or Nha Trang Seafood Company) NTACO Corporation (also known as NTACO or NTACO Corp.) NTSF Seafoods Joint Stock Company (also known as NTSF or NTSF Seafoods) Phu Thanh Hai Co. Ltd. (also known as PTH Seafood) PREFCO Distribution, LLC QMC Foods, Inc. Quang Minh Seafood Company Limited (also known as Quang Minh, Quang Minh Seafood Co., Ltd., or Quang Minh Seafood Co.) Quirch Foods, LLC QVD Food Company, Ltd. (also known as QVD, QVD Food Co., Ltd., or QVD Aquaculture)⁶ Riptide Foods Saigon-Mekong Fishery Co., Ltd. (also known as SAMEFICO or Saigon Mekong Fishery Co., Ltd.) Seafood Joint Stock Company No. 4 (also known as SEAPRIEXCO No. 4) Seafood Joint Stock Company No. 4 Branch Dongtam Fisheries Processing Company (also known as DOTASEAFOODCO or Seafood Joint Stock Company No. 4—Branch Dong Tam Fisheries Processing Company) Seavina Joint Stock Company (also known as Seavina) Southern Fishery Industries Company, Ltd. (also known as South Vina, South Vina Co., Ltd., Southern Fishery Industries Co., Ltd., Southern Fisheries Industries Company, Ltd., or Southern Fisheries Industries Company Limited) Sunrise Corporation TG Fishery Holdings Corporation (also known as TG) Thanh Hung Co., Ltd. (also known as Thanh Hung Frozen Seafood Processing Import Export Co., Ltd. or Thanh Hung) The Great Fish Company, LLC Thien Ma Seafood Co., Ltd. (also known as THIMACO, Thien Ma, Thien Ma Seafood Company, Ltd., or Thien Ma Seafoods Co., Ltd.) Thuan An Production Trading and Service Co., Ltd. (also known as TAFISHCO, Thuan An Production Trading and Services Co., Ltd., or Thuan An Production Trading & Service Co., Ltd.) Thuan Phuoc Seafoods and Trading Corporation To Chau Joint Stock Company (also known as TOCHAU, TOCHAU JSC, or TOCHAU Joint Stock Company) Viet Hai Seafood Company Limited (also known as Viet Hai, Viet Hai Seafood Co., Ltd., Viet Hai Seafood Co., Vietnam Fish-One Co., Ltd., or Fish One) Viet Phu Foods & Fish Co., Ltd. Viet Phu Foods and Fish Corporation (also known as Vietphu, Viet Phu, Viet Phu Food and Fish Corporation, or Viet Phu Food & Fish Corporation) Vietnam Seaproducts Joint Stock Company (also known as Seaprodex or Vietnam Seafood Corporation—Joint Stock Company) Vinh Long Import-Export Company (also known as Vinh Long, Imex Cuu Long, Vinh Long Import/Export Company) Vinh Quang Fisheries Corporation (also known as Vinh Quang, Vinh Quang Fisheries Corp., Vinh Quang Fisheries Joint Stock Company, or Vinh Quang Fisheries Co., Ltd.) Vietnam-Wide Entity</p>	
THAILAND: Steel Propane Cylinders, A-549-839	8/1/20-7/31/21
Sahamitr Pressure Container Public Company Limited	
THE PEOPLE'S REPUBLIC OF CHINA: Cast Iron Soil Pipe Fittings, A-570-062	8/1/20-7/31/21
Shijiazhuang Asia Casting Co., Ltd.	
Wor-Biz Industrial Product Co., Limited (Anhui)	
THE PEOPLE'S REPUBLIC OF CHINA: Hydrofluorocarbon Blends, A-570-028	8/1/20-7/31/21
Changshu 3F Zhonghao New Chemical Materials Co., Ltd.	
Daikin Fluorochemicals (China) Co., Ltd.	
Dongyang Weihua Refrigerants Co., Ltd.	
Electrochemical Factory of Zhejiang Juhua Co., Ltd.	
Fujian Qingliu Dongying Chemical Ind. Co., Ltd.	
Hongkong Richmax Ltd.	
Huantai Dongyue International Trade Co. Ltd.	

	Period to be reviewed
Icool International (Hong Kong) Limited Jiangsu Bluestar Green Technology Co., Ltd. Jiangsu Meilan Chemical Co., Ltd. Jiangsu Sanmei Chemicals Co., Ltd. Jinhua Binglong Chemical Technology Co., Ltd. Jinhua Yonghe Fluorochemical Co., Ltd. Liaocheng Fuer New Materials Technology Co., Ltd. Linhai Limin Chemicals Co., Ltd. Ninhua Group Co., Ltd. Puremann, Inc. Ruyuan Dongyangguang Fluorine Co., Ltd. Shandong Dongyue Chemical Co., Ltd. Shandong Huaan New Material Co., Ltd. Shandong Xinlong Science Technology Co., Ltd. Shanghai Aohong Chemical Co., Ltd. Sinochem Environmental Protection Chemicals (Taicang) Co., Ltd. Sinochem Lantian Fluoro Materials Co., Ltd. T.T. International Co., Ltd. Taizhou Huasheng New Refrigeration Material Co., Ltd. Taizhou Qingsong Refrigerant New Material Co., Ltd. Weitron International Refrigeration Equipment (Kunshan) Co., Ltd. Weitron International Refrigeration Equipment Co., Ltd. Zhejiang Fulai Refrigerant Co., Ltd. Zhejiang Guomao Industrial Co., Ltd. Zhejiang Lantian Environmental Protection Fluoro Material Co. Ltd. Zhejiang Lishui Fuhua Chemical Co., Ltd. Zhejiang Organic Fluor-Chemistry Plant, Zhejiang Juhua Co., Ltd. Zhejiang Quhua Fluor-Chemistry Co., Ltd. Zhejiang Quhua Juxin Fluorochemical Industry Co., Ltd. Zhejiang Quzhou Juxin Fluorine Chemical Co., Ltd. Zhejiang Quzhou Lianzhou Refrigerants Co., Ltd. Zhejiang Sanmei Chemical Industry Co., Ltd. Zhejiang Yonghe Refrigerant Co., Ltd. Zhejiang Zhiyang Chemical Co., Ltd. Zhejiang Zhonglan Refrigeration Technology Co., Ltd. Zibo Feiyuan Chemical Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Light-Walled Rectangular Pipe and Tube, A-570-914	8/1/20-7/31/21
Hangzhou Ailong Metal Product Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Passenger Vehicle and Light Truck Tires, A-570-016	8/1/20-7/31/21
Anhui Jichi Tire Co., Ltd. Crown International Corporation Giti Tire (Anhui) Company Ltd. Giti Tire (Fujian) Company Ltd. Giti Tire Global Trading Pte. Ltd. Hankook Tire China Co., Ltd. Hongtyre Group Co. Jiangsu Hankook Tire Co., Ltd. Kenda Rubber (China) Co., Ltd. Koryo International Industrial Limited Kumho Tire Co., Inc. Kumho Tire (Changchun) Co., Inc. Kumho Tire (Tanjin) Co., Inc. Mayrun Tyre (Hong Kong) Limited Nanjing Kumho Tire Co., Ltd. Nankang (Zhangjiagang Free Trade Zone) Rubber Industrial Co., Ltd. Qingdao Crowntyre Industries Co. Ltd Qingdao Lakesea Tyre Co., Ltd. Qingdao Nama Industrial Co., Ltd. Qingdao Odyking Tyre Co., Ltd. Qingdao Sentury Tyre Co., Ltd. Qingdao Sunfulcess Tyre Co., Ltd. Qingdao Transamerica Tire Industrial Co., Ltd. Roadclaw Tyre (Hong Kong) Limited Safe & Well (HK) International Trading Limited Sailun Group (HongKong) Co., Limited, formerly known as Sailun Jinyu Group (Hong Kong) Co., Limited Sailun Group Co., Ltd., formerly known as Sailun Jinyu Group Co., Ltd. Sailun Tire Americas Inc., formerly known as SJI North America Inc. Shandong Changfeng Tyres Co., Ltd. Shandong Duratti Rubber Corporation Co., Ltd. Shandong Haohua Tire Co., Ltd. Shandong Hengyu Science & Technology Co., Ltd. Shandong Linglong Tyre Co., Ltd. Shandong Longyue Rubber Co., Ltd.	

	Period to be reviewed
Shandong New Continent Tire Co., Ltd. Shandong Province Sanli Tire Manufactured Co., Ltd. Shandong Wanda Boto Tyre Co., Ltd. Shandong Yongsheng Rubber Group Co., Ltd. Shouguang Firemax Tyre Co., Ltd. Sumitomo Rubber (Changshu) Co., Ltd. Sumitomo Rubber (Hunan) Co., Ltd. Triangle Tyre Co., Ltd. Tyrechamp Group Co., Limited Wendeng Sanfeng Tyre Co., Ltd. Winrun Tyre Co., Ltd. Zhaoqing Junhong Co., Ltd. Zhongce Rubber Group Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Polyethylene Retail Carrier Bags, A-570-886	8/1/20-7/31/21
Crown Polyethylene Products (International) Ltd. Dongguan Nozawa Plastics Products Co., Ltd. and United Power Packaging, Ltd. (collectively Nozawa)	
THE PEOPLE'S REPUBLIC OF CHINA: Steel Nails, A-570-909	8/1/20-7/31/21
Dezhou Hualude Hardware Products Co., Ltd. Hebei Minmetals Co., Ltd. Huanghua Jinhai Hardware Products Co. Ltd. Huanghua Xionghua Hardware Products Co., Ltd. Jining Dragon Fasteners Co., Ltd. Jining Huarong Hardware Products Co., Ltd. Jining Yonggu Metal Products Co., Ltd. Nanjing Caiqing Hardware Co., Ltd. Nanjing Yuechang Hardware Co., Ltd. SDC International Australia Pty. Ltd. Shandong Oriental Cherry Hardware Group Heze Products Co., Ltd. Shandong Oriental Cherry Hardware Import and Export Co., Ltd. Shandong Qingyun Hongyi Hardware Products Co., Ltd. Shanghai Curvet Hardware Products Co., Ltd. Shanghai Yueda Nails Industry Co., Ltd., a.k.a. Shanghai Yueda Nails Co., Ltd. Shanxi Hairui Trade Co., Ltd. Shanxi Pioneer Hardware Industrial Co., Ltd. Shanxi Tianli Industries Co., Ltd. S-Mart (Tianjin) Technology Development Co., Ltd. Suntec Industries Co., Ltd. Tianjin Jinchi Metal Products Co., Ltd. Tianjin Jinghai County Hongli Industry & Business Co., Ltd., a.k.a. Tianjin Jinghai County Hongli Industry and Business Co., Ltd. Tianjin Jishili Hardware Products Co., Ltd. Tianjin Universal Machinery Imp. & Exp. Corporation Tianjin Zhitong Metal Products Co., Ltd. Tianjin Zhonglian Metals Ware Co., Ltd. Xi'an Metals and Minerals Import & Export Co., Ltd. Zhejiang Gem-Chun Hardware Accessory Co., Ltd.	
CVD Proceedings	
INDIA: Finished Carbon Steel Flanges, C-533-872	1/1/20-12/31/20
Adinath International Allena Group Alloyed Steel Balkrishna Steel Forge Pvt. Ltd. Bansidhar Chiranjilal Bebitz Flanges Works Private Limited C. D. Industries Cetus Engineering Private Limited CHW Forge CHW Forge Pvt. Ltd. Citizen Metal Depot Corum Flange DN Forge Industries Echjay Forgings Limited Falcon Valves and Flanges Private Limited Heubach International Hindon Forge Pvt. Ltd. Jai Auto Pvt. Ltd. Kinnari Steel Corporation Mascot Metal Manufacturers M F Rings and Bearing Races Ltd. Munish Forge Private Limited Norma (India) Ltd. OM Exports	

	Period to be reviewed
Punjab Steel Works Raaj Sagar Steels Ravi Ratan Metal Industries R.D. Forge R.N. Gupta & Co. Ltd. Rolex Fittings India Pvt. Ltd. Rollwell Forge Engineering Components and Flanges Rollwell Forge Pvt. Ltd. SHM (ShinHeung Machinery) Siddhagiri Metal & Tubes Sizer India Steel Shape India Sudhir Forgings Pvt. Ltd. Tirupati Forge Pvt. Ltd. Uma Shanker Khandelwal and Co. Umashanker Khandelwal Forging Limited USK Export Private Limited	
SPAIN: Ripe Olives, C-469-818 Aceitunas Guadalquivir, S.L.U. ⁷ Aceitunas Torrent, S.L. Agro Sevilla Aceitunas S.COOP Andalusia, a.k.a. Agro Sevilla Aceitunas, S.Coop. And. Angel Camacho Alimentacion S.L. ⁸ Alimentary Group Dcoop S.Coop. And., a.k.a. DCOOP, S.Coop. And.	1/1/20-12/31/20
SOCIALIST REPUBLIC OF VIETNAM: Utility Scale Wind Towers, C-552-826 CS Wind Corporation CS Wind Vietnam Co.	12/13/19-12/31/20
THE PEOPLE'S REPUBLIC OF CHINA: Cast Iron Soil Pipe Fittings, C-570-063 Shijiazhuang Asia Casting Co., Ltd.	1/1/20-12/31/20
THE PEOPLE'S REPUBLIC OF CHINA: Multilayered Wood Flooring, C-570-971 Kember Flooring Inc., a.k.a. Kember Hardwood Flooring, Inc. ⁹	1/1/19-12/31/19
THE PEOPLE'S REPUBLIC OF CHINA: Passenger Vehicle and Light Truck Tires, C-570-017 Hankook Tire China Co., Ltd. Jiangsu Hankook Tire Co., Ltd. Kumho Tire Co., Inc. Kumho Tire (Tanjin) Co., Inc. Kumho Tire (Changchun) Co., Inc. Mayrun Tyre (Hong Kong) Limited Nanjing Kumho Tire Co., Ltd. Prinx Chengshan (Shandong) Tire Company Ltd. Qingdao Lakesea Tyre Co., Ltd. Qingdao Nexen Tire Corporation Safe & Well (HK) International Trading Limited Sailun Group Co., Ltd., formerly known as Sailun Jinyu Group Co., Ltd. Sailun Group (HongKong) Co., Limited., formerly known as Sailun Jinyu Group (Hong Kong) Co., Limited. Sailun Tire Americas Inc., formerly known as SJI North America Inc. Shandong Haohua Tire Co., Ltd. Shandong Province Sanli Tire Manufactured Co., Ltd. Shandong Wanda Boto Tyre Co., Ltd. Sumitomo Rubber (Changshu) Co., Ltd. Sumitomo Rubber (Hunan) Co., Ltd. Triangle Tyre Co., Ltd. Zhaoqing Junhong Co., Ltd. Zhongce Rubber Group Co., Ltd	1/1/20-12/31/20

Suspension Agreements

None.

⁵ The Hung Vuong Group is a single entity comprised of the following individual companies: (1) An Giang Fisheries Import and Export Joint Stock Company (also known as Agifish, AnGiang Fisheries Import and Export, An Giang Fisheries Import & Export Joint Stock Company); (2) Asia Pangasius Company Limited (also known as ASIA); (3) Hung Vuong Ben Tre Seafood Processing Company Limited (also known as Ben Tre, HVBT, or HVBT Seafood Processing); (4) Europe Joint Stock Company (also known as Europe JSC or EJS CO.); (5) Hung Vuong Corporation (also known as HVC or HV Corp.); (6) Hung Vuong Mascato Company Limited; (7) Hung Vuong—Sa Dec Co.,

Ltd. (also known as Hung Vuong-Sa Dec Co., Ltd. or Hung Vuong Sa Dec Company Limited); and (8) Hung Vuong—Vinh Long Co., Ltd. (also known as Hung Vuong-Vinh Long Co., Ltd. or Hung Vuong Vinh Long Company Limited).

⁶ QVD Food Company, Ltd. is a single entity that also includes: (1) QVD Dong Thap Food Co., Ltd. (also known as Dong Thap or QVD DT); and (2) Thuan Hung Co., Ltd. (also known as THUFICO).

⁷ Commerce found this company to be cross owned with: Coromar Inv., S.L., AG Explotaciones Agrícolas, S.L.U., and Grupo Aceitunas Guadalquivir, S.L. *See Ripe Olives from Spain:*

Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order, 83 FR 37469, August 1, 2018.

⁸ Commerce previously found this company to be cross owned with Cuarterola S.L., Cucanoche S.L., and Grupo Angel Camacho Alimentacion. *See Ripe Olives from Spain: Final Results of Countervailing Duty Administrative Review; 2017-2018; Correction*, 86 FR 38269, July 20, 2021.

⁹ This company was inadvertently omitted from the initiation notice that published on February 4, 2021 (86 FR 8166).

	Period to be reviewed
Deferral of Initiation of Administrative Review	
INDONESIA: Utility Scale Wind Towers, ¹⁰ C-560-834 PT Kenertec Power System	12/13/19-12/31/20

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an AD order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), Commerce, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether AD duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant “gap” period of the order (*i.e.*, the period following the expiry of provisional measures and before definitive measures were put into place), if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce’s regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.*, the filing of

¹⁰ Pursuant to 19 CFR 351.213(c), Commerce received a request from PT Kenertec Power System to defer the administrative review of this CVD order with respect to itself for one year. Commerce did not receive any objections to the deferral within 15 days after the end of the anniversary month. As such, we will initiate the administrative review of this CVD order with respect to PT Kenertec Power System in the month immediately following the next anniversary month.

separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce’s regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the *Final Rule*,¹¹ available at <https://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt>, prior to submitting factual information in this segment. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.¹²

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information using the formats provided at the end of the *Final Rule*.¹³ Commerce intends to

¹¹ See *Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (*Final Rule*); see also the frequently asked questions regarding the *Final Rule*, available at https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.

¹² See *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19*, 85 FR 41363 (July 10, 2020).

¹³ See section 782(b) of the Act; see also *Final Rule*; and the frequently asked questions regarding the *Final Rule*, available at <https://enforcement>.

reject factual submissions in any proceeding segments if the submitting party does not comply with applicable certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by Commerce.¹⁴ In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) Q&V questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This policy also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. Please review the *Final Rule*, available at <https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the

[trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf](https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf).

¹⁴ See 19 CFR 351.302.

Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: October 1, 2021.

Scot Fullerton,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021-21900 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-351-842]

Certain Uncoated Paper From Brazil: Final Results of Antidumping Duty Administrative Review; 2019-2020

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

SUMMARY: The Department of Commerce (Commerce) determines that certain uncoated paper (uncoated paper) from Brazil was sold in the United States at less than normal value during the period of review (POR) March 1, 2019, through February 29, 2020.

DATES: Applicable October 7, 2021.

FOR FURTHER INFORMATION CONTACT:

Christopher Maciuba, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0413.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2021, Commerce published the *Preliminary Results*.¹ We invited interested parties to comment on the *Preliminary Results*.² This review covers one respondent: Suzano S.A. (Suzano).³ Although the petitioners⁴ and Suzano both submitted comments on the

¹ See *Certain Uncoated Paper from Brazil: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Successor-in-Interest Determination; 2019-2020*, 86 FR 30000 (June 4, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See *Preliminary Results*, 86 FR at 30002.

³ In the *Preliminary Results*, we determined that Suzano S.A. is the successor-in-interest to Suzano Papel e Celulose S.A. We did not receive comments from interested parties related to this finding. Accordingly, we continue to determine that it is the successor-in-interest. For additional information on Commerce's analysis regarding the successor-in-interest finding. See *Preliminary Results PDM* at 4.

⁴ The petitioners for this case are Domtar Corporation; P.H. Glatfelter Company; Packaging Corporation of America; and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, CLC.

Preliminary Results, each party subsequently withdrew its comments, leaving no arguments on the record to address. Accordingly, no party has commented on the *Preliminary Results* and the final results remain unchanged from the *Preliminary Results*.

Commerce conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order⁵

The merchandise covered by the *Order* includes uncoated paper in sheet form; weighing at least 40 grams per square meter but not more than 150 grams per square meter; that either is a white paper with a GE brightness level⁶ of 85 or higher, or is a colored paper; whether or not surface-decorated, printed (except as described below), embossed, perforated, or punched; irrespective of the smoothness of the surface; and irrespective of dimensions (Certain Uncoated Paper).

Certain Uncoated Paper includes: (a) Uncoated free sheet paper that meets this scope definition; (b) uncoated ground wood paper produces from bleached chemi-thermo-mechanical pulp (BCTMP) that meets this scope definition; and (c) any other uncoated paper that meets this scope definition regardless of the type of pulp used to produce the paper.

Specifically excluded from the scope are: (1) Paper printed with final content of printed text or graphics; and (2) lined paper products, typically school supplies, composed of paper that incorporates straight horizontal and/or vertical lines that would make the paper unsuitable for copying or printing purposes. For purposes of this scope definition, paper shall be considered "printed with final content" where at least one side of the sheet has printed text and/or graphics that cover at least five percent of the surface area of the entire sheet.

On September 1, 2017, Commerce determined that imports of uncoated

⁵ See *Certain Uncoated Paper from Australia, Brazil, Indonesia, the People's Republic of China, and Portugal: Amended Final Affirmative Antidumping Determinations for Brazil and Indonesia and Antidumping Duty Orders*, 81 FR 11174 (March 3, 2016) (*Order*).

⁶ One of the key measurements of any grade of paper is brightness. Generally speaking, the brighter the paper the better the contrast between the paper and the ink. Brightness is measured using a GE Reflectance Scale, which measures the reflection of light off a grade of paper. One is the lowest reflection, or what would be given to a totally black grade, and 100 is the brightest measured grade. "Colored paper" as used in this scope definition means a paper with a hue other than white that reflects one of the primary colors of magenta, yellow, and cyan (red, yellow, and blue) or a combination of such primary colors.

paper with a GE brightness of 83 +/- 1% (83 Bright paper), otherwise meeting the description of in-scope merchandise, constitute merchandise "altered in form or appearance in minor respects" from in-scope merchandise that are subject to the *Order*.⁷

Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 4802.56.1000, 4802.56.2000, 4802.56.3000, 4802.56.4000, 4802.56.6000, 4802.56.7020, 4802.56.7040, 4802.57.1000, 4802.57.2000, 4802.57.3000, and 4802.57.4000. Some imports of subject merchandise may also be classified under 4802.62.1000, 4802.62.2000, 4802.62.3000, 4802.62.5000, 4802.62.6020, 4802.62.6040, 4802.69.1000, 4802.69.2000, 4802.69.3000, 4811.90.8050 and 4811.90.9080.⁸ While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.

Final Results of the Review

We determine that the following weighted-average dumping margin exists for the respondent for the POR, March 1, 2019, through February 29, 2020:

Exporter/producer	Weighted-average dumping margin (percent)
Suzano S.A	19.40

⁷ See *Certain Uncoated Paper from Australia, Brazil, the People's Republic of China, Indonesia, and Portugal: Affirmative Final Determination of Circumvention of the Antidumping and Countervailing Duty Orders*, 82 FR 41610 (September 1, 2017).

⁸ On January 27, 2021, Commerce preliminarily found that rolls of certain uncoated paper from Brazil were being further processed in the United States into individual sheets of uncoated paper that would be subject to the *Order*. The uncoated paper rolls covered by the preliminary finding are converted into sheets of uncoated paper using specialized cutting machinery prior to printing, and are typically, but not exclusively, between 52 and 103 inches wide and 50 inches in diameter. These certain uncoated paper rolls are classified under HTSUS subheading 4802.55. See *Certain Uncoated Paper from Brazil: Affirmative Preliminary Determination of Circumvention of the Antidumping Duty Order for Uncoated Paper Rolls*, 86 FR 7261 (January 27, 2021). Commerce intends to make a final finding as to whether these uncoated paper rolls are within the scope of the *Order* after the issuance of the final results of this administrative review. Any entries of merchandise subject to the circumvention inquiry made during the POR will remain suspended until the conclusion of the circumvention proceeding.

Disclosure

As noted above, there are no comments on the record regarding Commerce's *Preliminary Results* to be addressed here. As a result, we have not modified our analysis from the *Preliminary Results*, and we will not issue a decision memorandum to accompany this **Federal Register** notice. We are adopting the *Preliminary Results* as the final results of this review. Further, because we have not changed our calculations since the *Preliminary Results*, there are no new calculations to disclose, in accordance with 19 CFR 351.224(b), for these final results.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. We will calculate importer-specific *ad valorem* assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements for estimated antidumping duties will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Suzano will be equal to its weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by a producer or exporter not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-

value (LTFV) investigation, but the producer has been covered in a prior completed segment of this proceeding, the cash deposit rate will be the company-specific rate established for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 27.11 percent,⁹ the all-others rate established in the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with section 751(a)(1) and 777(i) of the Act.

Dated: October 1, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021-21902 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB404]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

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

ACTION: Notice of issuance of Letters of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that three Letters of Authorization (LOA) have been issued to bp Exploration & Production Inc. (bp) for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico.

DATES: The LOAs are effective from January 1, 2022, through December 31, 2022.

ADDRESSES: The LOAs, LOA requests, and supporting documentation are available online at: www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico. In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds

⁹ See *Order*.

that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined “negligible impact” in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Except with respect to certain activities not pertinent here, the MMPA defines “harassment” as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively “industry operators”), in Federal waters of the U.S. Gulf of Mexico (GOM) over the course of 5 years (86 FR 5322; January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a

determination that the amount of take authorized under the LOA is of no more than small numbers.

Summary of Request and Analysis

Bp plans to conduct three separate geophysical surveys, and submitted an LOA request for each survey. Each survey is a 3D ocean bottom node (OBN) survey within a distinct bp prospect area. The surveys will occur within bp’s Atlantis, Mad Dog, and Puma prospect areas, respectively. See Table 1 and Figure 1 of the respective LOA applications for more information regarding the location of these areas.

For each survey, bp anticipates using an airgun array consisting of 32 elements, with a total volume of 5,110 cubic inches (in³). Please see bp’s applications for additional detail.

In addition to the previously described conventional airgun source arrays, bp would also use a proprietary low-frequency source (“Wolfspär”) to supplement the quantity and quality of data collected during each survey. The Wolfspär source was not evaluated through the rule. However, our rule anticipated the possibility of new and unusual technologies (NUT) and determined they would be evaluated on a case-by case basis (86 FR 5322, 5442; January 19, 2021). In this case, as described below, our evaluation of the source leads to a conclusion that no take of marine mammals is likely to occur as a result of the source’s use and, therefore, no additional review is necessary.

Wolfspär is a variable-frequency marine resonator that was developed to image subsurface features that are challenging to penetrate with other seismic sound sources. This source is designed to produce ultra-low frequency (from 1.4–16 Hz, but typically used to produce signals at 2–4 Hz) swept (non-impulsive) signals, and is used in tandem with conventional airgun acoustic sources. The Wolfspär source is towed at greater depth than conventional airgun sources (30–60 m compared with approximately 8–12 m). The system was tested in controlled environments in 2013–14, and an open-water system integration test was conducted in the GOM in 2014. Field trials were conducted in 2017–18. The Wolfspär source has since been used consistently in association with bp’s survey operations.

Wolfspär signal duration is tens of seconds, however, the total output of the Wolfspär source is less compared to the output of a typical large airgun array (1/1000th peak SPL; Dellinger *et al.*, 2016). Results of a sound source verification study conducted during the

2017–18 at-sea trials showed that (1) Wolfspär signals were consistently lower in amplitude than signals from the airgun array used in conjunction with Wolfspär, with frequency content mostly outside marine mammal hearing range, including their most susceptible hearing range for noise-induced hearing loss, and (2) signal amplitude was low enough that the Wolfspär source was often not detectable above background sound levels. Measured 12-second sound exposure level weighted for low-frequency cetaceans did not exceed 95 dB SEL (source level back-calculated assuming spherical spreading). The source produces harmonics (beyond the fundamental frequency of less than 17 Hz) of decreasing spectral amplitude up to 100 Hz. However, harmonics are at lower energy, and at higher frequencies (above the fundamental frequency) the dominant noise source is not the device itself, but the hydraulic power unit and the ship towing the device (absent concurrent use of conventional airgun sources). For reference, the hypothesized generalized hearing range of low-frequency cetaceans starts at 7 Hz, while those of mid- and high-frequency cetaceans are much higher (150 and 275 Hz, respectively), and the point of greatest sensitivity (*i.e.*, greatest susceptibility to noise-induced hearing loss) for these three groups is 1.7, 24, and 42 kHz, respectively. Therefore, marine mammals may not even detect the Wolfspär signals, much less suffer any consequences from exposure.

Because the source levels are lower than those of concurrently used airgun sources, and the frequency content of the signals is predominantly outside the hearing range of any marine mammal, NMFS concludes that use of the Wolfspär source presents no potential for impacts to marine mammals additional to those caused through use of the airgun array. Even absent concurrent airgun use, effects to marine mammals from the Wolfspär source are unlikely. Due to the signal characteristics of the sound source, *i.e.*, slow rise time and relatively low source levels, there is no potential for injury of marine mammals unless they occur at very close distances to the source (<10 m) for a prolonged continuous time period (*i.e.*, implausible circumstances). Broadband sounds produced by the vessel towing the Wolfspär source are expected to dominate the perceived soundscape (absent concurrent airgun use), masking sounds from Wolfspär at frequencies audible to marine mammals. NMFS considers impacts to marine mammals in association with use of the Wolfspär source to be discountable.

We also note that Wolfspaar was assessed in 2017 as a NUT as part of BOEM Permit L17-011 Mod 2, and accordingly underwent Endangered Species Act (ESA) section 7 step-down review at that time. Subsequently, Wolfspaar was again evaluated as a NUT and evaluated through step-down review under NMFS' 2020 Biological Opinion on the Federally Regulated Oil and Gas Program Activities in the Gulf of Mexico in association with BOEM Permit L20-026. As a result of this review, NMFS determined that use of the source is unlikely to result in additional effects beyond those previously considered in the 2020 Biological Opinion.

Consistent with the preamble to the final rule, the survey effort proposed by bp in its LOA requests was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (86 FR 5322, 5398; January 19, 2021). In order to generate the appropriate take number for authorization, the following information was considered: (1) Survey type; (2) location (by modeling zone¹); (3) number of days; and (4) season.² The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled survey type in each zone and season.

Summary descriptions of the modeled survey geometries (*i.e.*, 2D, 3D NAZ, 3D WAZ, Coil) are available in the preamble to the proposed rule (83 FR 29212, 29220; June 22, 2018). 3D NAZ was selected as the best available proxy survey type. The OBN surveys will employ bottom-mounted receivers, or "nodes," used in conjunction with a vessel-towed seismic source array. For each survey, bp will deploy up to 4,000 nodes which, when fully deployed, will cover approximately 400 km² of seafloor for a survey that covers an approximate sea surface area of 1,200 km². Two dual- or triple-source vessels will be used to produce acoustic pulses at regular spatial intervals across the node grid. The source vessels will survey along transect lines that extend through, and 10 km beyond, the node grid on each site. Note that all available acoustic exposure modeling results assume use of a 72-element, 8,000 in³ array. In this case, take numbers authorized through the LOAs are considered conservative (*i.e.*, they likely overestimate take)

¹ For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

² For purposes of acoustic exposure modeling, seasons include Winter (December–March) and Summer (April–November).

primarily due to differences in the airgun arrays planned for use by bp as compared to the array modeled for the rule.

Each survey will take place for up to 50 days. Each of the prospect areas is located in the central GOM, roughly on the boundary of Zones 5 and 7. For each survey, it is assumed that 75 percent would occur in Zone 5 and 25 percent in Zone 7. The described distribution was selected based on the location of the prospect areas (the majority of total prospect area coverage is in Zone 5, with some overlap into Zone 7). The season is not known in advance. Therefore, the take estimates for each species are based on the season that has the greater value for the species (*i.e.*, winter or summer). Because all three surveys are the same in terms of location (*i.e.*, within the same zones), duration, and survey type, the following discussion and resulting take analysis in Table 1 below apply to each survey.

For some species, take estimates based solely on the modeling yielded results that are not realistically likely to occur when considered in light of other relevant information available during the rulemaking process regarding marine mammal occurrence in the GOM. Thus, although the modeling conducted for the rule is a natural starting point for estimating take, our rule acknowledged that other information could be considered (see, *e.g.*, 86 FR 5322, 5442 (January 19, 2021), discussing the need to provide flexibility and make efficient use of previous public and agency review of other information and identifying that additional public review is not necessary unless the model or inputs used differ substantively from those that were previously reviewed by NMFS and the public). For these surveys, NMFS has other relevant information reviewed during the rulemaking that indicates use of the acoustic exposure modeling to generate a take estimate for certain marine mammal species produces results inconsistent with what is known regarding their occurrence in the GOM. Accordingly, we have adjusted the calculated take estimates as described below.

Rice's whales (formerly known as GOM Bryde's whales)³ are generally found within a small area in the northeastern GOM in waters between 100–400 meters (m) depth along the continental shelf break (Rosel *et al.*, 2016). Whaling records suggest that

³ The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.*, 2021).

Rice's whales historically had a broader distribution within similar habitat parameters throughout the GOM (Reeves *et al.*, 2011; Rosel and Wilcox, 2014), and a NOAA survey reported observation of a Rice's whale in the western GOM in 2017 (NMFS, 2018). Habitat-based density modeling identified similar habitat (*i.e.*, approximately 100–400 m water depths along the continental shelf break) as being potential Rice's whale habitat (Roberts *et al.*, 2016), although a "core habitat area" defined in the northeastern GOM (outside the scope of the rule) contained approximately 92 percent of the predicted abundance of Rice's whales. See discussion provided at, *e.g.*, 83 FR 29212, 29228, 29280 (June 22, 2018); 86 FR 5322, 5418 (January 19, 2021).

Although it is possible that Rice's whales may occur outside of their core habitat, NMFS expects that any such occurrence would be limited to the narrow band of suitable habitat described above (*i.e.*, 100–400 m). Bp's planned activity will occur in water depths of approximately 1,200–2,300 m in the central GOM. Based on that information, NMFS does not expect there to be the reasonable potential for take of Rice's whale in association with these surveys and, accordingly, does not authorize take of Rice's whale through these LOAs.

Killer whales are the most rarely encountered species in the GOM, typically in deep waters of the central GOM (Roberts *et al.*, 2015; Maze-Foley and Mullin, 2006). The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each modeling zone. NMFS has determined that the approach results in unrealistic projections regarding the likelihood of encountering killer whales.

As discussed in the final rule, the density models produced by Roberts *et al.* (2016) provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. GOM. The predictions represent the output of models derived from multi-year observations and associated environmental parameters that incorporate corrections for detection bias. However, in the case of killer whales, the model is informed by few data, as indicated by the coefficient of variation associated with the abundance predicted by the model (0.41, the second-highest of any GOM species model; Roberts *et al.*, 2016). The model's authors noted the expected

non-uniform distribution of this rarely-encountered species (as discussed above) and expressed that, due to the limited data available to inform the model, it “should be viewed cautiously” (Roberts *et al.*, 2015).

NOAA surveys in the GOM from 1992–2009 reported only 16 sightings of killer whales, with an additional 3 encounters during more recent survey effort from 2017–18 (Waring *et al.*, 2013; www.boem.gov/gommapps). Two other species were also observed on fewer than 20 occasions during the 1992–2009 NOAA surveys (Fraser’s dolphin and false killer whale⁴). However, observational data collected by protected species observers (PSOs) on industry geophysical survey vessels from 2002–2015 distinguish the killer whale in terms of rarity. During this period, killer whales were encountered on only 10 occasions, whereas the next most rarely encountered species (Fraser’s dolphin) was recorded on 69 occasions (Barkaszi and Kelly, 2019). The false killer whale and pygmy killer whale were the next most rarely encountered species, with 110 records each. The killer whale was the species with the lowest detection frequency during each period over which PSO data were synthesized (2002–2008 and 2009–2015). This information qualitatively informed our rulemaking process, as discussed at 86 FR 5322, 5334 (January 19, 2021), and similarly informs our analysis here.

The rarity of encounter during seismic surveys is not likely to be the product of high bias on the probability of detection. Unlike certain cryptic species with high detection bias, such as *Kogia* spp. or beaked whales, or deep-diving species with high availability bias, such as beaked whales or sperm whales, killer whales are typically available for detection when present and are easily observed. Roberts *et al.* (2015) stated that availability is not a major factor affecting detectability of killer whales from shipboard surveys, as they are not a particularly long-diving species. Baird *et al.* (2005) reported that mean dive durations for 41 fish-eating killer whales for dives greater than or equal to 1 minute in duration was 2.3–2.4 minutes, and Hooker *et al.* (2012) reported that killer whales spent 78 percent of their

time at depths between 0–10 m. Similarly, Kvadsheim *et al.* (2012) reported data from a study of four killer whales, noting that the whales performed 20 times as many dives 1–30 m in depth than to deeper waters, with an average depth during those most common dives of approximately 3 m.

In summary, killer whales are the most rarely encountered species in the GOM and typically occur only in particularly deep water. While this information is reflected through the density model informing the acoustic exposure modeling results, there is relatively high uncertainty associated with the model for this species, and the acoustic exposure modeling applies mean distribution data over areas where the species is in fact less likely to occur. NMFS’ determination in reflection of the data discussed above, which informed the final rule, is that use of the generic acoustic exposure modeling results for killer whales will generally result in estimated take numbers that are inconsistent with the assumptions made in the rule regarding expected killer whale take (86 FR 5322, 5403; January 19, 2021).

In past authorizations, NMFS has often addressed situations involving the low likelihood of encountering a rare species such as killer whales in the GOM through authorization of take of a single group of average size (*i.e.*, representing a single potential encounter). See 83 FR 63268, December 7, 2018. See also 86 FR 29090, May 28, 2021; 85 FR 55645, September 9, 2020. For the reasons expressed above, NMFS determined that a single encounter of killer whales is more likely than the model-generated estimates and has authorized take associated with a single killer whale group encounter (*i.e.*, up to 7 animals) for each LOA.

Based on the results of our analysis, NMFS has determined that the level of taking expected for each of these surveys and authorized through the LOAs is consistent with the findings made for the total taking allowable under the regulations. See Table 1 in this document and Table 9 of the final rule (86 FR 5322; January 19, 2021).

Small Numbers Determinations

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed “small numbers.” In short, when an acceptable estimate of the individual

marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small. For more information please see NMFS’ discussion of the MMPA’s small numbers requirement provided in the final rule (86 FR 5322, 5438; January 19, 2021).

The take numbers for each authorization are determined as described above. Subsequently, the total incidents of harassment for each species may be multiplied by scalar ratios to produce a derived product that better reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the likelihood that some individual marine mammals may be taken on more than one day (see 86 FR 5322, 5404; January 19, 2021). The output of this scaling, where appropriate, is incorporated into an adjusted total take estimate that is the basis for NMFS’ small numbers determinations, as depicted in Table 1.

This product is used by NMFS in making the necessary small numbers determinations, through comparison with the best available abundance estimates (see discussion at 86 FR 5322, 5391; January 19, 2021). For this comparison, NMFS’ approach is to use the maximum theoretical population, determined through review of current stock abundance reports (SAR; www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments) and model-predicted abundance information (<https://seamap.env.duke.edu/models/Duke/GOM/>). For the latter, for taxa where a density surface model could be produced, we use the maximum mean seasonal (*i.e.*, three-month) abundance prediction for purposes of comparison as a precautionary smoothing of month-to-month fluctuations and in consideration of a corresponding lack of data in the literature regarding seasonal distribution of marine mammals in the GOM. Information supporting the small numbers determinations is provided in Table 1. (Note that, because take numbers for each of the three surveys are the same, the small numbers analysis applies to each survey).

⁴ However, note that these species have been observed over a greater range of water depths in the GOM than have killer whales.

TABLE 1—TAKE ANALYSIS PER SURVEY/LOA

Species	Authorized take	Scaled take ¹	Abundance ²	Percent abundance
Rice's whale	0	n/a	51	n/a
Sperm whale	1,712	724.1	2,207	32.8
<i>Kogia</i> spp	³ 635	215.4	4,373	4.9
Beaked whales	8,404	848.8	3,768	22.5
Rough-toothed dolphin	1,208	346.8	4,853	7.1
Bottlenose dolphin	5,689	1,632.9	176,108	0.9
Clymene dolphin	3,823	1,097.3	11,895	9.2
Atlantic spotted dolphin	2,205	632.8	74,785	0.8
Pantropical spotted dolphin	19,751	5,668.4	102,361	5.5
Spinner dolphin	4,211	1,208.6	25,114	4.8
Striped dolphin	1,551	445.0	5,229	8.5
Fraser's dolphin	448	128.5	1,665	7.7
Risso's dolphin	1,089	321.3	3,764	8.5
Melon-headed whale	2,467	727.8	7,003	10.4
Pygmy killer whale	582	171.6	2,126	8.1
False killer whale	871	257.0	3,204	8
Killer whale	7	n/a	267	2.6
Short-finned pilot whale	648	191.1	1,981	9.6

¹ Scalar ratios were applied to "Authorized Take" values as described at 86 FR 5322, 5404 (January 19, 2021) to derive scaled take numbers shown here.

² Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.*, 2016). For those taxa where a density surface model predicting abundance by month was produced, the maximum mean seasonal abundance was used. For those taxa where abundance is not predicted by month, only mean annual abundance is available. For Rice's whale and the killer whale, the larger estimated SAR abundance estimate is used.

³ Includes 17 takes by Level A harassment and 618 takes by Level B harassment. Scalar ratio is applied to takes by Level B harassment only; small numbers determination made on basis of scaled Level B harassment take plus Level A harassment take.

Based on the analysis contained herein of bp's proposed survey activity described in its LOA applications and the anticipated take of marine mammals, NMFS finds that for each issued LOA small numbers of marine mammals will be taken relative to the affected species or stock sizes (*i.e.*, less than one-third of the best available abundance estimate) and therefore the taking is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for these LOA requests is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under each of the LOAs is of no more than small numbers. Accordingly, we have issued three LOAs to bp authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Kimberly Damon-Randall,

Director, Office of Protected Resources,
National Marine Fisheries Service.

[FR Doc. 2021-21935 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB486]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Scientific and Statistical Committee (SSC).

DATES: The SSC meeting will be held via webinar October 27–29, 2021. The meeting will be held from 8:30 a.m. until 5 p.m. EDT on October 27 and October 28, 2021, and from 8:30 a.m. until 12:30 p.m. EST on October 29, 2021.

ADDRESSES: The meeting will be held via webinar.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571-4366 or toll free: (866) SAFMC-10; fax:

(843) 769-4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The meeting is open to the public via webinar as it occurs. Webinar registration is required. Information regarding webinar registration will be posted to the Council's website at: <http://safmc.net/safmc-meetings/scientific-and-statistical-committee-meetings/> as it becomes available. The meeting agenda, briefing book materials, and online comment form will be posted to the Council's website two weeks prior to the meeting. Written comment on SSC agenda topics is to be distributed to the Committee through the Council office similar to all other briefing materials. For this meeting, the deadline for submission of written comment is 12 p.m., October 29, 2021.

Agenda Items

The SSC will review the SEDAR (Southeast Data Assessment and Review) 68 scamp grouper Research Track stock assessment; SEDAR 71: Gag grouper projections requested at the September 2021 Council meeting; and review and approve scopes of work for upcoming 2024 SEDAR assessments. SSC members will also review an Ecopath with Ecosim model forecasting ecosystem impacts of increased recruitment of red snapper; aspects of the Council's Acceptable Biological Catch (ABC) Control Rule; and Standardized Bycatch Reporting

Methodology (SBRM). The SSC will discuss the preliminary findings of the Catch Level Projections Workgroup, recommend regional case studies for the national SSC meeting, and address other topics as needed.

The SSC will provide guidance to staff and make recommendations for Council consideration as appropriate.

Multiple opportunities for comment on agenda items will be provided during SSC meetings. Open comment periods will be provided at the start of the meeting and near the conclusion. Those interested in providing comment should indicate such in the manner requested by the Chair, who will then recognize individuals to provide comment.

Additional opportunities for comment on specific agenda items will be provided, as each item is discussed, between initial presentations and SSC discussion. Those interested in providing comment should indicate such in the manner requested by the Chair, who will then recognize individuals to provide comment. All comments are part of the record of the meeting.

Although non-emergency issues not contained in the meeting 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 SAFMC 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: October 4, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-21913 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB496]

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 (Council) is scheduling a joint public meeting of its Scallop Advisory Panel 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 Tuesday, October 26, 2021, at 9 a.m. Webinar registration URL information: <https://attendee.gotowebinar.com/register/8067792331180250384>.

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:

Agenda

The Advisory Panel will Discuss Framework 34: Receive an update and provide input on a range of potential access area and DAS allocations for the 2022 and 2023 fishing years. Framework 34 will set specifications including ABC/ACLs, days-at-sea, access area allocations, total allowable landings for the Northern Gulf of Maine (NGOM) management area, targets for General Category incidental catch, General Category access area trips, and set-asides for the observer and research programs for fishing year 2022 and default specifications for fishing year 2023. Framework 34 will implement measures proposed by the Council through Amendment 21 to the Scallop FMP. They will also receive an update on the evaluation of rotational management project. The panel will develop recommendations for possible 2022 scallop work priorities. Other business will be discussed, if 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: October 4, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-21917 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB495]

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 (Council) is scheduling a joint public meeting of its Scallop Committee 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 Wednesday, October 27, 2021, at 9 a.m. Webinar registration URL information: <https://attendee.gotowebinar.com/register/2059004166337959696>.

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:**Agenda**

The Committee will discuss Framework 34: Receive an update and provide input on a range of potential access area and DAS allocations for the 2022 and 2023 fishing years. Framework 34 will set specifications including ABC/ACLs, days-at-sea, access area allocations, total allowable landings for the Northern Gulf of Maine (NGOM) management area, targets for General Category incidental catch, General Category access area trips, and set-asides for the observer and research programs for fishing year 2022 and default specifications for fishing year 2023. Framework 34 will implement measures proposed by the Council through Amendment 21 to the Scallop FMP. They will also receive an update on the evaluation of rotational management project. The committee will develop recommendations for possible 2022 scallop work priorities. Other business will be discussed, if 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: October 4, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-21914 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648-XB490]

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 will hold a webinar question and answer session for stakeholders regarding electronic vessel trip reporting (eVTR) in preparation for required commercial electronic reporting.

DATES: The question and answer session will be held via webinar on Tuesday, October 26, 2021, beginning at 5 p.m. For details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: This meeting will be held via webinar and connection and agenda information will be posted at the MAFMC's website: <https://www.mafmc.org/council-events>.

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

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

SUPPLEMENTARY INFORMATION: This is a Council-hosted eVTR question and answer session open to the public and targeted towards commercial operators. Beginning on November 10, 2021, all commercial vessels with federal permits for species managed by the Mid-Atlantic or New England Council will be required to submit vessel trip reports (VTRs) electronically as eVTRs within 48 hours of the end of a trip (unless required sooner as with some sector allocations). This action does not change any other existing requirements associated with VTRs. These changes were recommended by the MAFMC and NEFMC in order to increase the timeliness and availability of data submitted through VTRs, reduce the reporting burden on commercial vessel operators, and increase the accuracy and quality of data. This meeting follows multiple Council held training workshops and will act as an opportunity for follow up questions

regarding using an approved eVTR software application.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Spedden at the Mid-Atlantic Council Office (302) 526-5251 at least 5 days prior to the meeting date.

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

Dated: October 4, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021-21918 Filed 10-6-21; 8:45 am]

BILLING CODE 3510-22-P

COMMODITY FUTURES TRADING COMMISSION**Sunshine Act Meetings**

TIME AND DATE: 1:00 p.m. EDT, Thursday, October 14, 2021.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Enforcement matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.cftc.gov/>.

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202-418-5964.

Authority: 5 U.S.C. 552b.

Dated: October 5, 2021.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2021-22038 Filed 10-5-21; 4:15 pm]

BILLING CODE 6351-01-P

COUNCIL OF THE INSPECTORS GENERAL ON INTEGRITY AND EFFICIENCY**Senior Executive Service Performance Review Board Membership; correction**

AGENCY: Council of the Inspectors General on Integrity and Efficiency (CIGIE).

ACTION: Notice; correction.

SUMMARY: CIGIE published a document in the **Federal Register** of Friday, October 1, 2021, setting forth the names and titles of the current membership of the CIGIE Performance Review Board. The information contained in the document was outdated.

FOR FURTHER INFORMATION CONTACT:

Individual Offices of Inspectors General at the telephone numbers listed below.

DATES: October 1, 2021.

SUPPLEMENTARY INFORMATION:**Correction**

In the **Federal Register** of Friday, October 1, 2021 in FR Doc. 2021–21383, pages 54438 through 54442, the information in its entirety was outdated. The current information is provided below.

I. Background

The Inspector General Act of 1978, as amended, created the Offices of Inspectors General as independent and objective units to conduct and supervise audits and investigations relating to Federal programs and operations. The Inspector General Reform Act of 2008, established the Council of the Inspectors General on Integrity and Efficiency (CIGIE) to address integrity, economy, and effectiveness issues that transcend individual Government agencies; and increase the professionalism and effectiveness of personnel by developing policies, standards, and approaches to aid in the establishment of a well-trained and highly skilled workforce in the Offices of Inspectors General. The CIGIE is an interagency council whose executive chair is the Deputy Director for Management, Office of Management and Budget, and is comprised principally of the 75 Inspectors General (IGs).

II. CIGIE Performance Review Board

Under 5 U.S.C. 4314(c)(1)–(5), and in accordance with regulations prescribed by the Office of Personnel Management, each agency is required to establish one or more Senior Executive Service (SES) performance review boards. The purpose of these boards is to review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive. The current members of the Council of the Inspectors General on Integrity and Efficiency Performance Review Board, as of October 1, 2021, are as follows:

Agency for International Development

Phone Number: (202) 712–1150

CIGIE Liaison—Thomas Ullom (202) 712–1150

Thomas Ullom—Deputy Inspector General and Acting Inspector General.

Nicole Angarella—General Counsel to the Inspector General.

Justin Brown—Counselor to the Inspector General (SL).

Suzann Gallaher—Assistant Inspector General for Investigations.

Marc Meyer—Deputy Assistant Inspector General for Investigations.

Thomas Yatsco—Assistant Inspector General for Audit.

Alvin A. Brown—Deputy Assistant Inspector General for Audit.

Toayoa Aldridge—Deputy Assistant Inspector General for Audit.

Sabrina Ferguson-Ward—Assistant Inspector General for Management.

Willie (Will) Young—Deputy Assistant Inspector General for Management.

Department of Agriculture

Phone Number: (202) 720–8001

CIGIE Liaison—Angel N. Bethea (202) 720–8001

Ann M. Coffey—Deputy Inspector General.

Christy A. Slamowitz—Counsel to the Inspector General.

Gilroy Harden—Assistant Inspector General for Audit.

Steven H. Rickrode, Jr.—Deputy Assistant Inspector General for Audit.

Yarisis Rivera Rojas—Deputy Assistant Inspector General for Audit.

Kevin Tyrrell—Assistant Inspector General for Investigation.

Peter P. Paradis, Sr.—Deputy Assistant Inspector General for Investigations.

Virginia E. B. Rone—Assistant Inspector General for Analytics and Innovation.

Department of Commerce

Phone Number: (202) 280–8374

CIGIE Liaison—Jacqueline G. Ruley (202) 280–8374

Roderick M. Anderson—Deputy Inspector General.

Richard L. Bachman—Assistant Inspector General for Audit and Evaluation.

E. Wade Green—Counsel to the Inspector General.

Robert O. Johnston, Jr.—Chief of Staff.

Scott M. Kieffer—Assistant Inspector General for Investigations.

Frederick J. Meny—Assistant Inspector General for Audit & Evaluation.

Arthur L. Scott, Jr.—Assistant Inspector General for Audit and Evaluation.

Mark H. Zabarsky—Principle Assistant Inspector General for Audit and Evaluation.

Council of the Inspectors General on Integrity and Efficiency

Phone Number: (202) 292–2600

CIGIE Liaison—Denise Mangra (202) 292–2604

Alan F. Boehm—Executive Director.
Douglas Holt—Executive Director
CIGIE Training Institute.

Department of Defense

Phone Number: (703) 604–8324

Acting CIGIE Liaison—Brett Mansfield (703) 604–8300

Daniel R. Blair—Deputy Chief of Staff.
Leo J. Fitzharris IV—Assistant IG for Strategic Planning and Performance.
Marguerite C. Garrison—Deputy Inspector General for Administrative Investigations.

Carol N. Gorman—Assistant Inspector General for Readiness and Cyber Operations.

Paul Hadjiyane—General Counsel.
Theresa S. Hull—Assistant Inspector General for Acquisition and Sustainment Management.

James R. Ives—Deputy Inspector General for Overseas Contingency Operations.

Kelly P. Mayo—Deputy Inspector General for Investigations.

Troy M. Meyer—Principal Assistant Inspector General for Audit.

Michael J. Roark—Deputy Inspector General for Evaluations.

Steven A. Stebbins—Chief of Staff.
Paul K. Sternal—Assistant Inspector General for Investigations/Investigative Ops.

Randolph R. Stone—Assistant Inspector General for Space, Intelligence, Engineering and Oversight.
Richard B. Vasquez—Assistant Inspector General for Readiness & Global Operations.

Lorin T. Venable—Assistant Inspector General for Financial Management and Reporting.

David G. Yacobucci—Assistant Inspector General for Data Analytics.

Michael C. Zola—Assistant Inspector General for Legislative Affairs & Communications.

Department of Education

Phone Number: (202) 245–6900

CIGIE Liaison—Catherine Grant (202) 245–7023

Bryon Gordon—Assistant Inspector General for Audit.

Sean Dawson—Deputy Assistant Inspector General for Audit.

Aaron Jordan—Assistant Inspector General for Investigations.

Shafee Carnegie—Deputy Assistant Inspector General for Investigations.

Robert Mancuso—Assistant Inspector General for Information Technology Audits and Computer Crime Investigations.

Kevin Young—Deputy Assistant Inspector General for Assistant Inspector General for Information Technology Audits and Computer Crime Investigations.

Francine Hines—Assistant Inspector General for Management Services.

Antigone Potamianos—Counsel to the Inspector General.

Department of Energy

Phone Number: (202) 586-4393

CIGIE Liaison—Ryan Cocolin (202) 586-8672

Jennifer Quinones—Deputy Inspector General.

Nicholas Acker—Counsel to the Inspector General.

Virginia Grebasch—Senior Counsel, FOIA and Privacy Act Officer.

Travis Farris—Special Counsel for Administrative Remedies.

Charles Sabatos—Assistant Inspector General for Management and Administration.

Lewe Sessions—Assistant Inspector General for Investigations.

Kenneth Dieffenbach—Deputy Inspector General for Investigations.

Sarah Nelson—Assistant Inspector General for Technology, Financial and Analytics.

Earl Omer—Assistant Inspector General for Audits.

Jack Rouch—Deputy Assistant Inspector General for Audits.

John McCoy II—Deputy Assistant Inspector General for Audits.

Anthony Cruz—Assistant Inspector General for Inspections, Intelligence Oversight, and Special Projects.

Environmental Protection Agency

CIGIE Liaison—Jennifer Kaplan (202) 566-0918

Charles Sheehan—Deputy Inspector General.

Edward Shields—Associate Deputy Inspector General.

Mary Katherine Trimble—Assistant Inspector General for Audit and Evaluation.

Laura Nicolosi—Principal Deputy Assistant Inspector General for Audit and Evaluation.

M. Benjamin May—Counsel.

Equal Employment Opportunity Commission

Phone Number: 1-800-849-4230

CIGIE Liaison—Joyce T. Willoughby (202) 921-3138

Milton A. Mayo, Jr.—Inspector General.

Federal Labor Relations Authority

Phone Number: (202) 218-7744

CIGIE Liaison—Dana Rooney (202) 218-7744

Dana Rooney—Inspector General.

Federal Maritime Commission

Phone Number: (202) 523-5863

CIGIE Liaison—Jon Hatfield (202) 523-5863

Jon Hatfield—Inspector General.

Federal Trade Commission

Phone Number: (202) 326-2355

CIGIE Liaison—Andrew Katsaros (202) 326-2355

Andrew Katsaros—Inspector General.

General Services Administration

Phone Number: (202) 501-0450

CIGIE Liaison—Phyllis Goode (202) 273-7270

Robert C. Erickson—Deputy Inspector General.

Larry L. Gregg—Associate Inspector General.

Edward Martin—Counsel to the Inspector General.

R. Nicholas Goco—Assistant Inspector General for Audits.

Barbara Bouldin—Deputy Assistant Inspector General for Acquisition Program Audits.

Brian Gibson—Deputy Assistant Inspector General for Real Property Audits.

James E. Adams—Assistant Inspector General for Investigations.

Patricia D. Sheehan—Assistant Inspector General for Inspections.

Kristine Preece—Assistant Inspector General for Administration.

Department of Health and Human Services

Phone Number: (202) 619-3148

CIGIE Liaison—Elise Stein (202) 619-2686

Juliet Hodgkins—Acting Chief of Staff.

Robert Owens, Jr.—Deputy Inspector General for Management and Policy.

Gerald Caron III—Assistant Inspector General/Chief Information Officer.

Gregg Treml—Assistant Inspector General/Deputy Chief Financial Officer.

Gary Cantrell—Deputy Inspector General for Investigations.

Elton Malone—Assistant Inspector General for Investigations.

Christian Schrank—Assistant Inspector General for Investigations.

Suzanne Murrin—Deputy Inspector General for Evaluation and Inspections.

Erin Bliss—Assistant Inspector General for Evaluation and Inspections.

Ann Maxwell—Assistant Inspector General for Evaluation and Inspections.

Gregory Demske—Chief Counsel to the Inspector General.

Robert DeConti—Assistant Inspector General for Legal Affairs.

Lisa Re—Assistant Inspector General for Legal Affairs.

Amy Frontz—Deputy Inspector General for Audit Services.

Tamara Lilly—Assistant Inspector General for Audit Services.

Department of Homeland Security

Phone Number: (202) 981-6000

CIGIE Liaison—E. William Baxter (202) 321-4357

Kristen Bernard—Assistant Inspector General for Information Technology Audits.

Jordan Gottfried—Assistant Inspector General for Management.

Department of Housing and Urban Development

Phone Number: (202) 708-0430

CIGIE Liaison—Michael White (202) 402-8410

Charles Jones—Senior Advisor for External Affairs.

Fara Damelin—Chief of Staff.

Kimberly Randall—Deputy Assistant Inspector General for Audit.

Kilah White—Assistant Inspector General for Audit.

Kudawashe Ushe—Chief Information Officer.

Maura Malone—Counsel to the Inspector General.

Brian Pattison—Assistant Inspector General for Evaluation.

Matthew Harris—Deputy Assistant Inspector General for Investigation.

Jacquelyn Phillips—Chief Strategy Officer.

Stephen Begg—Deputy Inspector General.

International Development Finance Corporation

Phone Number: (202) 408-6246

CIGIE Liaison—Gladis Griffith (202) 408-8562

Anthony Zakel—Inspector General (SL).

Gladis Griffith—Deputy Inspector General & General Counsel (SL).

John Warren—Assistant Inspector General of Investigations (SL).

Darrell Benjamin—Assistant Inspector General of Audits (SL).

Department of the Interior

Phone Number: (202) 208-5635

CIGIE Liaison—Karen Edwards (202) 208-5635

Caryl Brzymialkiewicz—Deputy Inspector General.

Matthew Elliott—Assistant Inspector General for Investigations.

Edward “Ted” Baugh—Deputy Assistant Inspector General for Investigations.

Bruce Delaplaine—General Counsel.
Stephen Hardgrove—Assistant Inspector General for Strategic Programs.

Jorge Christian—Assistant Inspector General for Management.

Department of Justice

Phone Number: (202) 514-3435

CIGIE Liaison—John Lavinsky (202) 514-3435

William M. Blier—Deputy Inspector General.

Jonathan M. Malis—General Counsel.
Michael Sean O’Neill—Assistant Inspector General for Oversight and Review.

Patricia A. Sumner—Deputy Assistant Inspector General for Oversight and Review.

Jason R. Malmstrom—Assistant Inspector General for Audit.

Mark L. Hayes—Deputy Assistant Inspector General for Audit.

Sarah E. Lake—Assistant Inspector General for Investigations.

Sandra D. Barnes—Deputy Assistant Inspector General for Investigations.

Donald L. Kyzar—Assistant Inspector General for Information Technology Division.

Rene L. Lee—Assistant Inspector General for Evaluation and Inspections.

Gregory T. Peters—Assistant Inspector General for Management and Planning.

Cynthia Sjoberg Radway—Deputy Assistant Inspector for Management and Planning.

Department of Labor

Phone Number: (202) 693-5100

CIGIE Liaison—Luiz A. Santos (202) 693-7062

Larry D. Turner—Deputy Inspector General (Acting Inspector General).

Dee Thompson—Counsel to the Inspector General.

Carolyn Ramona Hantz—Assistant Inspector General for Audit.

Ray Armada—Deputy Assistant Inspector General for Audit.

Michael C. Mikulka—Assistant Inspector General for Investigations—Labor Racketeering and Fraud.

James D. Powell—Deputy Assistant Inspector General for Investigations—Labor Racketeering and Fraud.

Tara A. Porter—Assistant Inspector General for Management and Policy.

Claudette L. Fogg-Castillo—Deputy Assistant Inspector General for Management and Policy.

Thomas D. Williams—Chief Technology Officer.

Luiz A. Santos—Assistant Inspector General for Congressional and Public Relations.

Jessica Southwell—Chief Performance and Risk Management Officer.

National Aeronautics and Space Administration

Phone Number: (202) 358-1220

CIGIE Liaison—Renee Juhans (202) 358-1712

George A. Scott—Deputy Inspector General.

Frank LaRocca—Counsel to the Inspector General.

Kimberly F. Benoit—Assistant Inspector General for Audits.

Ross W. Weiland—Assistant Inspector General for Management Planning.

National Archives and Records Administration

Phone Number: (301) 837-3000

CIGIE Liaison—John Simms (301) 837-3000

Brett Baker—Inspector General.
Jewel Butler—Assistant Inspector General for Audit.

Jason Metrick—Assistant Inspector General for Investigations.

National Labor Relations Board

Phone Number: (202) 273-1960

CIGIE Liaison—Robert Brennan (202) 273-1960

David P. Berry—Inspector General.

National Science Foundation

Phone Number: (703) 292-7100

CIGIE Liaison—Lisa Vonder Haar (703) 292-2989

Megan Wallace—Assistant Inspector General for Investigations.

Mark Bell—Assistant Inspector General for Audits.

Ken Chason—Counsel to the Inspector General.

Nuclear Regulatory Commission

Phone Number: (301) 415-5930

CIGIE Liaison—Christine Arroyo (301) 415-0526

Malion Bartley, Assistant Inspector General for Investigations.

Office of Personnel Management

Phone Number: (202) 606-1200

CIGIE Liaison—Faiza Mathon-Mathieu (202) 606-2236

Norbert E. Vint—Deputy Inspector General/Deputy Inspector General Performing the Duties of the Inspector General.

Michael R. Esser—Assistant Inspector General for Audits.

Melissa D. Brown—Deputy Assistant Inspector General for Audits.

Lewis F. Parker, Jr.—Deputy Assistant Inspector General for Audits.

Drew M. Grimm—Assistant Inspector General for Investigations.

James L. Ropelewski—Assistant Inspector General for Management.

Nicholas E. Hoyle—Deputy Assistant Inspector General for Management.

Paul St. Hillaire—Assistant Inspector General for Legal and Legislative Affairs.

Robin A. Thottungal—Chief Information Technology Officer.

Special Inspector General for Pandemic Recovery

Phone Number: (202) 923-7782

CIGIE Liaison—Sarah Breen (202) 923-7782

Theodore R. Stehney—Assistant Inspector General for Auditing.

Michael T. Ryan—Assistant Inspector General for Investigations.

Peace Corps

Phone Number: (202) 692-2900

CIGIE Liaison—Joaquin Ferrao (202) 692-2921

Kathy Buller—Inspector General (Foreign Service).

Joaquin Ferrao—Deputy Inspector General and Legal Counsel (Foreign Service).

United States Postal Service

Phone Number: (703) 248-2100

CIGIE Liaison—Agapi Doulaveris (703) 248-2286

Elizabeth Martin—General Counsel.

Mark Duda—Assistant Inspector General for Mission Support/Chief Financial Officer.

Railroad Retirement Board

Phone Number: (312) 751-4690

CIGIE Liaison—Jill Roellig (312) 751-4993

Patricia A. Marshall—Deputy Inspector General and Counsel to the Inspector General.

Debra Stringfellow-Wheat—Assistant Inspector General for Audit.

Paul Palumbo—Assistant Inspector General for Investigations.

Small Business Administration

Phone Number: (202) 401-0753

CIGIE Liaison—Mary Kazarian (202) 205-6586

Brian Grossman—Assistant Inspector General for Investigations.

Andrea Deadwyler—Assistant Inspector General for Audits.

Sheldon Shoemaker—Assistant Inspector General for Management and Operations.

Social Security Administration

Phone Number: (410) 966-8385

CIGIE Liaison—Craig Mekler (443) 316-7922

Benjamin S. Alpert—Deputy Inspector General.

B. Chad Bungard—Chief of Staff/Chief Strategy Officer (Acting).

Jennifer Walker—Assistant Inspector General for Investigations.

Sotiris Planzos—Chief Investigative Counsel.

Kevin Huse—Deputy Assistant Inspector General for Investigations.

Donald Jefferson—Deputy Assistant Inspector General for Investigations.

Mark Franco—Deputy Assistant Inspector General for Investigations.

Michelle L. Anderson—Assistant Inspector General for Audit.

Jeffrey Brown—Deputy Assistant Inspector General for Audit.

Michael Arbuco—Assistant Inspector General of Information Technology.

Adriana Menchaca-Gendron—Assistant Inspector General of Resource Management.

Andrew Cannarsa—Deputy Assistant Inspector General of Resource Management.

Michelle M. Murray—Chief Counsel to the Inspector General.

Special Inspector General for the Troubled Asset Relief Program

Phone Number: (202) 622-1419

CIGIE Liaison—Melissa Bruce (202) 617-4238

Melissa Bruce—Principal Deputy Special Inspector General.

Thomas Jankowski—Deputy Inspector General for Investigations.

Gabriele Tonsil—Acting Deputy Inspector General for Audits.

Department of State and the U.S. Agency for Global Media

Phone Number: (571) 348-3804

CIGIE Liaison—Mark Huffman (571) 348-4881

Diana R. Shaw—Deputy Inspector General.

Parisa Salehi—Chief of Staff.

Norman P. Brown—Assistant Inspector General for Audits.

Sandra J. Lewis—Assistant Inspector General for Inspections.

Matthew Tuchow—General Counsel.

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Pauletta Battle—Deputy Assistant Inspector General for Financial Management and Transparency Audits.

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Heather Hill—Deputy Inspector General for Inspections and Evaluations.

Michael McKenney—Deputy Inspector General for Audit.

Nancy LaManna—Assistant Inspector General for Audit, Management, Planning, and Workforce Development.

Russell Martin—Assistant Inspector General for Audit, Returns Processing, and Accounting Services.

Danny Verneuille—Assistant Inspector General for Audit, Security, and Information Technology Services.

Matthew Weir—Assistant Inspector General for Audit, Compliance, and Enforcement Operations.

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Management and Administration/Chief Technology Officer.

Kathrine Smith—Assistant Inspector General for Special Reviews.

Dated: October 4, 2021.

Alan F. Boehm,

Executive Director.

[FR Doc. 2021-21888 Filed 10-6-21; 8:45 am]

BILLING CODE 6820-C9-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

South Atlantic Coastal Study Notice of Availability of Draft Report

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that the U.S. Army Corps of Engineers (USACE), South Atlantic Division, is issuing the *South Atlantic Coastal Study (SACS) Draft Report* and appendices. These documents will be available to the public for review and comment beginning on October 15, 2021. The documents will be available on the South Atlantic Division's website at: <https://www.sad.usace.army.mil/SACS/>.

DATES: Written comments must be submitted on or before November 8, 2021.

ADDRESSES: U.S. Army Corps of Engineers, Jacksonville District, ATTN: CESAJ-PM-W (SACS), 701 San Marco Blvd., Jacksonville, FL 32207-8175.

You may submit comments by any of the following methods:

SurveyMonkey: https://www.surveymonkey.com/r/SACS_comments.

Email: SACS@usace.army.mil.

Mail: U.S. Army Corps of Engineers, Jacksonville District, ATTN: CESAJ-PM-W (SACS), 701 San Marco Blvd., Jacksonville, FL 32207-8175.

FOR FURTHER INFORMATION CONTACT: South Atlantic Coastal Study Outreach Lead, Ms. Lisa Clark, at 904-232-2114 or by email at Lisa.M.Clark@usace.army.mil.

SUPPLEMENTARY INFORMATION: Congress authorized and funded the South Atlantic Coastal Study (SACS) in 2016, as Hurricanes Harvey, Irma, and Maria carried particular impact within the area of responsibility of the U.S. Army Corps of Engineers' (USACE) South Atlantic Division. The SACS followed on the heels of the successful completion of the North Atlantic Coast Comprehensive Study, a regional study conducted by

the USACE North Atlantic Division in the wake of the devastation caused by Hurricane Sandy in 2012. The SACS is a comprehensive coastal study focused on managing coastal storm risk to populations, infrastructure, and environmental resources throughout the coastal areas of North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Puerto Rico, and the U.S. Virgin Islands. These areas represent approximately 65,000 miles of tidally influenced shoreline. The goals of the SACS, authorized by Section 1204 of the Water Resources Development Act of 2016 (WRDA 2016), are to (1) provide a common operating picture of coastal risk, (2) identify high-risk locations and focus current and future resources, (3) identify and assess risk reduction actions, (4) promote and support resilient coastal communities, (5) promote sustainable projects and programs, and (5) leverage supplemental actions. In addition, the study identifies activities warranting further analysis and institutional barriers to implementation. Although the study also identifies those areas warranting more detailed evaluations, the SACS is not scoped to recommend projects for Congressional authorization or develop detailed project designs. Accordingly, National Environmental Policy Act (NEPA) documentation is not included in the study scope. Full NEPA and other environmental compliance would be accomplished as appropriate as part of future detailed evaluations before any actions could be implemented. The SACS also includes products intended to provide a consistent set of tools to enhance decision-making by all stakeholders. The products include current and projected wave and water elevation data for the study area, coastal Geographic Information Systems (GIS) analyses, economic evaluations, regional sediment management and sand availability determinations, environmental and cultural resource evaluations, and actionable risk reduction strategies in areas with coastal risk. Comments are encouraged on the SACS Draft Report and Appendices; technical SACS products are posted for reference as supporting materials.

In October 2021, the USACE will host virtual public meetings to discuss the report and answer questions. For more information on the virtual public meetings, visit: <https://www.sad.usace.army.mil/SACS/>. As the SACS does not contain project-level environmental compliance documentation, responses to individual public comment will not be provided.

However, feedback from public review will be considered in report finalization.

Larry D. McCallister,

Director of Programs, South Atlantic Division.

[FR Doc. 2021-21911 Filed 10-6-21; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF EDUCATION

[Docket No. ED-2021-SCC-0093]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Higher Education Emergency Relief Fund (HEERF) I, II and III Data Collection Form

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 a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before November 8, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection request by selecting "Department of Education" under "Currently Under Review," then check "Only Show ICR for Public Comment" checkbox. Comments may also be sent to ICDocketmgr@ed.gov.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Karen Epps, (202) 453-6337.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in

public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Higher Education Emergency Relief Fund (HEERF) I, II and III Data Collection Form.

OMB Control Number: 1840-0850.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 4,879.

Total Estimated Number of Annual Burden Hours: 195,160.

Abstract: This information collection requests approval for a revision to a previously approved collection that includes annual reporting requirements for the Higher Education Emergency Relief Fund (HEERF) program and obtains information on how the funds were used. Under the current unprecedented national health emergency, the legislative and executive branches of government have come together to offer relief to those individuals and industries affected by the COVID-19 virus under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the Coronavirus Response and Relief Supplemental Appropriations Act (CRRSAA), and the American Rescue Plan (ARP). Targeted relief to institutions of higher education (IHEs) has been made available under the HEERF program. HEERF, originally established by Section 18004(a) of the CARES Act, Public Law 116-136 (March 27, 2020) and expanded through CRRSAA and ARP, authorizes the Secretary of Education to allocate formula grant funds to participating IHEs to address impacts of the COVID-19 virus.

Dated: October 1, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021-21874 Filed 10-6-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21-134-000.

Applicants: SR Perry, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of SR Perry, LLC.

Filed Date: 9/30/21.

Accession Number: 20210930-5279.

Comment Date: 5 p.m. ET 10/21/21.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21-264-000.

Applicants: PGR 2021 Lessee 1, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of PGR 2021 Lessee 1, LLC.

Filed Date: 9/30/21.

Accession Number: 20210930-5208.

Comment Date: 5 p.m. ET 10/21/21.

Docket Numbers: EG21-265-000.

Applicants: NET Power, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of NET Power, LLC.

Filed Date: 9/30/21.

Accession Number: 20210930-5254.

Comment Date: 5 p.m. ET 10/21/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21-2349-002.

Applicants: AR Searcy Project

Company, LLC.
Description: Tariff Amendment: AR Searcy Supplement to be effective 9/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930-5194.

Comment Date: 5 p.m. ET 10/7/21.

Docket Numbers: ER21-2350-002.

Applicants: MS Sunflower Project

Company, LLC.
Description: Tariff Amendment: MS Sunflower Deficiency Response to be effective 9/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930-5195.

Comment Date: 5 p.m. ET 10/21/21.

Docket Numbers: ER21-2526-001.

Applicants: New York Independent

System Operator, Inc.
Description: Compliance filing: NYISO compliance errata to its 7/27/21 filing re: Order No. 676 NAESB WEQ to be effective 12/31/9998.

Filed Date: 10/1/21.

Accession Number: 20211001-5149.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER21-2986-000.

Applicants: Arizona Public Service Company.

Description: Notice of Cancellation of Service Agreement No. 234 with PacifiCorp of Arizona Public Service Company.

Filed Date: 9/29/21.

Accession Number: 20210929-5184.

Comment Date: 5 p.m. ET 10/20/21.

Docket Numbers: ER21-2987-000.

Applicants: Duke Energy Progress, LLC.

Description: § 205(d) Rate Filing:

DEP-NCEMPA Revisions to Rate Schedule No. 200 to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930-5183.

Comment Date: 5 p.m. ET 10/21/21.

Docket Numbers: ER21-2988-000.

Applicants: Public Service Company of New Mexico.

Description: § 205(d) Rate Filing: PNM Modifications to OATT Schedule 2 to be effective 3/31/2021.

Filed Date: 9/30/21..

Accession Number: 20210930-5188.

Comment Date: 5 p.m. ET 10/21/21.

Docket Numbers: ER21-2991-000.

Applicants: Consumers Energy

Company.

Description: Notice of Cancellation of Market Based Rate Tariff of Exeter Entergy Limited Partnership.

Filed Date: 9/30/21.

Accession Number: 20210930-5209.

Comment Date: 5 p.m. ET 10/21/21.

Docket Numbers: ER22-1-000.

Applicants: Alliant Energy Corporate Services, Inc.

Description: § 205(d) Rate Filing: AECS Schedule 2 Update (Burlington) to be effective 11/30/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5013.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-10-000.

Applicants: Maverick Wind Project, LLC.

Description: Tariff Amendment: FERC Electric Tariff No. 1 to be effective 10/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5074.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-11-000.

Applicants: Janis Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5075.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-12-000.

Applicants: Puckett Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5080.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-13-000.

Applicants: Regan Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5083.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-14-000.

Applicants: Darby Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5084.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-15-000.

Applicants: ELP Stillwater Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5085.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-16-000.

Applicants: Pattersonville Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5086.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-17-000.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: Third Amendment LGIA Aratina Solar Center 1 SA No. 198 TOT773 to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5092.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-18-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2021-10-01 PSCo-OMID-E&P-662-0.0.0 to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5104.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-19-000.

Applicants: Stanly Solar, LLC.

Description: Baseline eTariff Filing: Stanly Solar, LLC MBR Tariff to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5110.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-2-000.

Applicants: Midcontinent

Independent System Operator, Inc., International Transmission Company.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021-10-01_ITC Depreciation Rate Filing to be effective 1/1/2022.

Filed Date: 10/1/21.

Accession Number: 20211001-5029.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-20-000.

Applicants: PGR 2021 Lessee 1, LLC.

Description: Baseline eTariff Filing: PGR 2021 Lessee 1, LLC MBR Tariff to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5111.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-21-000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: UMPA TSOA Rev 6 to be effective 11/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5115.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-22-000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: BPA NITSA—(Idaho Falls Power) Rev 5 to be effective 10/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5146.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-23-000.

Applicants: Public Service Company of New Mexico.

Description: § 205(d) Rate Filing: Proposed Modifications to PNM's Open Access Transmission Tariff to be effective 12/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5153.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-24-000.

Applicants: System Energy Resources, Inc.

Description: § 205(d) Rate Filing: SERI UPSA Pension Filing to be effective 12/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5162.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-25-000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2021-10-01 EIM Entity Agreement—Bonneville Power Admin to be effective 12/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5166.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-3-000.

Applicants: Midcontinent

Independent System Operator, Inc., ITC Midwest LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System

Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021-10-01_ITCM Depreciation Rate Filing to be effective 1/1/2022.

Filed Date: 10/1/21.

Accession Number: 20211001-5031.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-4-000.

Applicants: Midcontinent

Independent System Operator, Inc., Michigan Electric Transmission Company, LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021-10-01_METC Depreciation Rate Filing to be effective 1/1/2022.

Filed Date: 10/1/21.

Accession Number: 20211001-5032.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-5-000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: CCSF Appendix E Revision to Extend Unmetered Load Eligibility (SA 275) to be effective 12/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5044.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-6-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA 6203; Queue No. AF2-398 to be effective 9/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5060.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-7-000.

Applicants: Branscomb Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5065.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-8-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1628R19 Western Farmers Electric Cooperative NITSA NOA to be effective 9/1/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5068.

Comment Date: 5 p.m. ET 10/22/21.

Docket Numbers: ER22-9-000.

Applicants: Grissom Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/2/2021.

Filed Date: 10/1/21.

Accession Number: 20211001-5069.

Comment Date: 5 p.m. ET 10/22/21.

The filings are accessible in the Commission's eLibrary system (<https://>

elibrary.ferc.gov/idmws/search/fercgensearch.asp by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: October 1, 2021.
Kimberly D. Bose,
Secretary.
 [FR Doc. 2021-21943 Filed 10-6-21; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD21-10-000]

Modernizing Electricity Market Design; Supplemental Notice of Technical Conference on Energy and Ancillary Services in the Evolving Electricity Sector

As first announced in the Notice of Technical Conference issued in this

proceeding on July 14, 2021, the Federal Energy Regulatory Commission (Commission) will convene a staff-led technical conference in the above-referenced proceeding on October 12, 2021, from approximately 9:00 a.m. to 5:00 p.m. Eastern time. The conference will be held remotely. Attached to this Supplemental Notice is an agenda for the technical conference, which includes the final conference program and expected speakers. Commissioners may attend and participate in the technical conference.

Discussions at the conference may involve issues raised in proceedings that are currently pending before the Commission. These proceedings include, but are not limited to:

	Docket No.
Tenaska Virginia Partners, L.P	ER10-1626-012.
Tenaska Power Services Co	ER10-1632-018.
Wheelbrator Frackville Energy Company, Inc	ER10-3237-011.
Calpine Vineland Solar, LLC	ER10-2036-011.
Calpine New Jersey Generation, LLC	ER10-2040-010.
Calpine Mid Merit, LLC	ER10-2041-010.
Calpine Mid-Atlantic Generation, LLC	ER10-2043-010.
Zion Energy LLC	ER10-2044-010.
Calpine Bethlehem, LLC	ER10-2051-010.
Bayonne Energy Center, LLC	ER11-3460-012.
TAQA Gen X LLC	ER11-4393-008.
Wheelbrator Baltimore, L.P	ER13-1485-011.
Red Oak Power, LLC	ER14-477-002.
Wheelbrator Falls, Inc	ER14-1777-010.
LQA, LLC	ER16-733-007.
Calpine Mid Merit II, LLC	ER18-1321-003.
Tenaska Pennsylvania Partners, LLC	ER18-1960-003.
California Independent System Operator Corporation	ER21-2455-000.
New York Independent System Operator, Inc	ER21-2460-000.
Midcontinent Independent System Operator, Inc	ER21-2486-000; ER21-2487-000.
PJM Interconnection, L.L.C	ER21-2582-000.
Midcontinent Independent System Operator, Inc	ER21-2620-000.
Southwest Power Pool, Inc	ER21-2676-000.
Midcontinent Independent System Operator, Inc	ER21-2677-000.
Midcontinent Independent System Operator, Inc	ER21-2720-000.
California Independent System Operator Corporation	ER21-2779-000.
Midcontinent Independent System Operator, Inc	ER21-2788-000.
Midcontinent Independent System Operator, Inc	ER21-2797-000.
Midcontinent Independent System Operator, Inc	ER21-2801-000.
American Electric Power Service Corporation v. Midcontinent Independent System Operator, Inc., Southwest Power Pool, Inc.	EL17-89-000.
PJM Interconnection, L.L.C	EL19-58, et al.; ER19-1486, et al.
City of Prescott, Arkansas v. Southwestern Electric Power Company, Midcontinent Independent System Operator, Inc ...	EL19-60-000.
PJM Interconnection, L.L.C	EL21-78-000, et al.
Basin Electric Power Cooperative and North Iowa Municipal Cooperative Association v. Southwest Power Pool, Inc	EL21-90-000.

The conference will be open for the public to attend remotely. There is no fee for attendance. Information on this technical conference, including a link to the webcast, will be posted on the conference's event page on the Commission's website (<https://www.ferc.gov/news-events/events/technical-conference-regarding-energy->

[and-ancillary-services-markets-10122021](https://www.ferc.gov/news-events/events/technical-conference-regarding-energy-and-ancillary-services-markets-10122021)) prior to the event. The conference will be transcribed. Transcripts will be available for a fee from Ace Reporting (202-347-3700).

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please

send an email to accessibility@ferc.gov or call toll free 1-866-208-3372 (voice) or 202-208-8659 (TTY), or send a fax to 202-208-2106 with the required accommodations.

For more information about this technical conference, please contact Emma Nicholson at emma.nicholson@ferc.gov or (202) 502-8741, or Alexander

Smith at alexander.smith@ferc.gov or (202) 502-6601. For legal information, please contact Adam Eldean at adam.eldean@ferc.gov or (202) 502-8047. For information related to logistics, please contact Sarah McKinley at sarah.mckinley@ferc.gov or (202) 502-8368. This notice is issued and published in accordance with 18 CFR 2.1.

Dated: October 1, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-21946 Filed 10-6-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15-904-003.
Applicants: Gas Transmission Northwest.
Description: Petition for Approval of Settlement of Gas Transmission Northwest LLC under RP15-904.
Filed Date: 09/29/21.
Accession Number: 20210929-5159.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1001-002.
Applicants: Texas Eastern Transmission, LP.
Description: Submits tariff filing per 154.203: Response to Show Cause (RP21-1001) Compliance Filing to be effective 12/31/21.
Filed Date: 09/30/2021.
Accession Number: 20210930-5184.
Comment Date: 10/12/21.
Docket Numbers: RP21-1150-000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: Wyoming Interstate Company, L.L.C. submits tariff filing per 154.203: Operational Purchase and Sale Report for Young Gas 2021 to be effective N/A under RP21-1150.
Filed Date: 09/28/21.
Accession Number: 20210928-5040.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1173-000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Amendment to a Negotiated Rate Agreement Filing—ConocoPhillips Company to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5001.

Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1174-000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: APL 2021 Fuel Filing to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5009.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1175-000.
Applicants: Saltville Gas Storage Company L.L.C.
Description: § 4(d) Rate Filing: SGSC 2021 Fuel Filing to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5010.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1176-000.
Applicants: Carolina Gas Transmission, LLC.
Description: § 4(d) Rate Filing: CGT—2021 FRQ and TDA Report to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5011.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1177-000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 10-1-2021 to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5027.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1178-000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20210930 Negotiated Rate to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5030.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1179-000.
Applicants: Trunkline Gas Company, LLC.
Description: § 4(d) Rate Filing: Fuel Filing on 9-30-21 to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5031.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1180-000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rates—Northern Utilities Releases to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5032.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1181-000.
Applicants: Panhandle Eastern Pipe Line Company, LP.
Description: § 4(d) Rate Filing: Fuel Filing on 9-30-21 to be effective 11/1/2021.

Filed Date: 9/30/21.
Accession Number: 20210930-5033.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1182-000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Fuel Filing on 9-30-21 to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5034.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1183-000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Various October 1 Capacity Releases to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5035.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1184-000.
Applicants: Trunkline Gas Company, LLC.
Description: Compliance filing: Annual Report of Flow Through filed 9-30-21 to be effective N/A.
Filed Date: 9/30/21.
Accession Number: 20210930-5036.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1185-000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various eff 10-1-2021) to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5037.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1186-000.
Applicants: Tallgrass Interstate Gas Transmission, LLC.
Description: § 4(d) Rate Filing: TIGT 2021-09-30 Negotiated Rate Agreement Termination to be effective 10/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5074.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1187-000.
Applicants: Eastern Gas Transmission and Storage, Inc.
Description: § 4(d) Rate Filing: EGTS—2021 Section 4 General Rate Case (1 of 3) to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5075.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1188-000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: TETLP SEP 2021 Rate Case Filing to be effective 11/1/2021.
Filed Date: 9/30/21.
Accession Number: 20210930-5076.
Comment Date: 5 p.m. ET 10/12/21.
Docket Numbers: RP21-1189-000.

Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: Penalty Revenue Crediting Report to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5078.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1190–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: SNG Housekeeping Filing 2021 to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5082.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1191–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Formula Based Negotiated Rate—10/1/2021 Update to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5087.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1192–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Spire South System Negotiated Rate to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5088.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1193–000.

Applicants: MoGas Pipeline LLC.

Description: § 4(d) Rate Filing: MoGas Ameren Negotiated Rate Agreement Filing to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5089.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1194–000.

Applicants: Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: VPSE—139080 Rev 4 Neg/Conf—Conf Agreement to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5100.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1195–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreements Filing (EOG_CIMA Nov 21) to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5103.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1196–000.

Applicants: LA Storage, LLC.

Description: § 4(d) Rate Filing: Filing of Negotiated Rate, Conforming IW Agreements 10.1.21 to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5105.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1197–000.

Applicants: National Fuel Gas Supply Corporation.

Description: § 4(d) Rate Filing: GT&C Section 42 PS/GHG Tracker Filing to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5137.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1198–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: § 4(d) Rate Filing: MNUS FRQ 2021 Filing to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5156.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1199–000.

Applicants: LA Storage, LLC.

Description: Annual Penalty Disbursement Report of LA Storage, LLC under RP21–1199.

Filed Date: 9/30/21.

Accession Number: 20210930–5160.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1200–000.

Applicants: Cheniere Corpus Christi Pipeline, LP.

Description: Compliance filing: CCCP Semi-Annual Transportation Retainage Adjustment Filing to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5163.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1201–000.

Applicants: Dauphin Island Gathering Partners.

Description: § 4(d) Rate Filing: Negotiated Rate Filing 9–30–2021 to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5171.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1202–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Oct 2021 to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5174.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1203–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: REX 2021–09–30 Definition and Service Request Revisions to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5181.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1204–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—MarketLink_Six One Vega to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5187.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1205–000.

Applicants: Dominion Energy Overthrust Pipeline, LLC.

Description: § 4(d) Rate Filing: WIC Non-conforming TSA Amendments to be effective 10/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5196.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1206–000.

Applicants: Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: COR Non-Conform Agreement to be effective 11/1/2021.

Filed Date: 9/30/21.

Accession Number: 20210930–5199.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1207–000.

Applicants: MoGas Pipeline LLC.

Description: Annual Report on Revenue from Penalties Subject to Crediting of MoGas Pipeline LLC under RP21–1207.

Filed Date: 9/30/21.

Accession Number: 20210930–5211.

Comment Date: 5 p.m. ET 10/12/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date.

Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP21–1187–000.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description: Report Filing: EGTS—2021 Section 4 General Rate Case (2 of 3) to be effective N/A.

Filed Date: 9/30/21.

Accession Number: 20210930–5091.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–1187–000.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description: Report Filing: EGTS—2021 Section 4 General Rate Case (3 of 3) to be effective N/A.

Filed Date: 9/30/21.

Accession Number: 20210930–5096.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: RP21–867–001.

Applicants: Cheniere Corpus Christi Pipeline, LP.

Description: Compliance filing: RP21–867 Updated Cost and Revenue Study to be effective N/A.

Filed Date: 9/30/21.

Accession Number: 20210930–5097.

Comment Date: 5 p.m. ET 10/12/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 1, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021–21944 Filed 10–6–21; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PL21–3–000]

Technical Conference on Greenhouse Gas Mitigation: Natural Gas Act Sections 3 and 7 Authorizations; Supplemental Notice of Technical Conference

As announced in the Notice of Technical Conference issued in this proceeding on September 16, 2021, the Federal Energy Regulatory Commission (Commission) will convene a Commission staff-led technical conference to discuss methods natural gas companies may use to mitigate the effects of direct and indirect greenhouse gas emissions resulting from Natural Gas Act sections 3 and 7 authorizations. The technical conference will be held on Friday, November 19, 2021, from approximately 9:00 a.m. to 3:30 p.m. Eastern time. The conference will be held virtually.

The agenda for this event is attached. The conference will be open for the public to attend virtually, and there is no fee for attendance. A second supplemental notice will be issued prior to the conference with the confirmed panelists. Information on this technical conference will also be posted on the

Calendar of Events on the Commission's website, www.ferc.gov, prior to the event. Transcripts will be available for a fee from Ace Reporting, (202) 347–3700.

Individuals interested in participating as panelists should self-nominate by 5:00 p.m. Eastern Time on Friday, October 8, 2021, at: GHGTechConf@ferc.gov. The self-nominations should have "Panelist Self-Nomination" in the subject line and include the panelist's: Name, title, organization, mailing address, telephone number, email address, one paragraph biography, photograph, and panel selection.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov, call toll-free (866) 208–3372 (voice) or (202) 208–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

For more information about this technical conference, please contact GHGTechConf@ferc.gov. For information related to logistics, please contact Sarah McKinley at sarah.mckinley@ferc.gov or (202) 502–8368.

Dated: October 1, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021–21947 Filed 10–6–21; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–463–000]

Texas Eastern Transmission, LP; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Holbrook Compressor Units Replacement Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document, that will discuss the environmental impacts of the Holbrook Compressor Units Replacement Project (Project) involving abandonment, construction, and operation of facilities by Texas Eastern Transmission, LP (Texas Eastern) in Greene County, Pennsylvania. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as "scoping." The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on November 1, 2021. Comments should be submitted in written form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all comments during the preparation of the environmental document.

If you submitted comments on this Project to the Commission before the opening of this docket on June 17, 2021, you will need to file those comments in Docket No. CP21–463–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this proposed Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable

easement agreement. You are not required to enter into an agreement. However, if the Commission approves the Project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Texas Eastern provided landowners with a fact sheet prepared by the FERC entitled “An Interstate Natural Gas Facility On My Land? What Do I Need To Know?” which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission’s proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas Questions or Landowner Topics link.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” You will be asked to select the type of filing you are making; a comment on a particular project is considered a “Comment on a Filing”; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the Project docket number (CP21–463–000)

on your letter. 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.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

Summary of the Proposed Project

Texas Eastern proposes to abandon 12 existing reciprocating compressor units dating from the 1950s, and replace them with 2 new units, at its existing Holbrook Compressor Station (Station). Texas Eastern’s stated purpose for this Project is to ensure the continued safe and reliable operation of the Station, while meeting all current air emissions requirements. Texas Eastern states that the 12 existing reciprocating units are outdated and seeks to replace them with two new, more efficient units. The two new compressor units proposed for this Project would utilize Solar’s SoLoNO_x dry low emissions technology for the control of oxides of nitrogen; and the new units would be equipped with oxidation catalysts for the control of carbon monoxide, volatile organic compounds, and organic hazardous air pollutants.

The general location of the Project is shown in appendix 1.¹

Land Requirements for Construction

Constructing the Project would require the temporary use of a total of about 39.8 acres of land. About 33.5 acres of workspace would be within the existing fence line of the Station. About

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called “eLibrary”. For instructions on connecting to eLibrary, refer to the last page of this notice. 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 assistance, contact FERC at FercOnlineSupport@ferc.gov or call toll free, (886) 208–3676 or TTY (202) 502–8659.

1.4 acres would be outside of the Station fence line. Texas Eastern also proposes to use about 4.8 acres at a temporary construction yard, the Bristoria Wareyard, for staging of materials and equipment. This yard is owned by Texas Eastern.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the abandonment, construction, and operation of the proposed Project under the relevant general resource areas:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- protected species;
- cultural resources;
- land use;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed Project or portions of the Project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff’s independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then 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 EA or draft and final EIS will be available in electronic format in the public record through eLibrary² and the

² For instructions on connecting to eLibrary, refer to the last page of this notice.

Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environmental-environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the Pennsylvania State Historic Preservation Office, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Project's potential effects on historic properties.⁴ The environmental document for this Project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Indian tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project and includes a mailing address with their comments. Commission staff will update the 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 number CP21-463-000 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 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number 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.

Public sessions or site visits will be posted on the Commission's calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

Dated: October 1, 2021.

Kimberly D. Bose,
Secretary.

[FR Doc. 2021-21945 Filed 10-6-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19-477-000]

Mountain Valley Pipeline, LLC; Notice of Extension of Time Request

Take notice that on September 29, 2021, Mountain Valley Pipeline, LLC (Mountain Valley) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until October 13, 2022, to place the Greene Interconnect in service.

Mountain Valley states that the Greene Interconnect facilities were mechanically complete and ready for service in late February 2021.¹ Mountain Valley is unable to place the Greene Interconnect in service until the Mountain Valley mainline facilities are completed. Mountain Valley has not completed construction of the mainline due to unforeseen litigation and permitting which Mountain Valley says is needed to provide natural gas flows to the Greene Interconnect. The Commission issued an order on October 9, 2020 granting Mountain Valley an extension of time until October 13, 2022 to complete construction and place the mainline facilities in service.² To align project completion deadlines, Mountain Valley requests that an extension of time until October 13, 2022 to place the Greene Interconnect in service.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Mountain Valley'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).³

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

¹ See Weekly Construction Report No. 23, Docket No. CP19-477-000 (filed March 25, 2021).

² *Mountain Valley Pipeline, LLC*, 173 FERC ¶ 61,026 (2020).

³ 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 The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations (CFR), Part 1501.8.

⁴ The Advisory Council on Historic Preservation's regulations are at 36 CFR 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

contested,⁴ the Commission will aim to issue an order acting on the request within 45 days.⁵ The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.⁶ 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.⁷ 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.⁸ 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 "eFile" link at <http://www.ferc.gov>.

⁴ Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2019).

⁵ *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 40 (2020).

⁶ *Id.* at P 40.

⁷ 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.

⁸ *Algonquin Gas Transmission, LLC*, 170 FERC ¶ 61,144, at P 40 (2020).

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 October 18, 2021.

Dated: October 1, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021-21942 Filed 10-6-21; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2021-0669; FRL-9116-01-OAR]

Phasedown of Hydrofluorocarbons: Notice of 2022 Allowance Allocations for Production and Consumption of Regulated Substances Under the American Innovation and Manufacturing Act of 2020

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has issued calendar year 2022 allowances for the production and consumption of hydrofluorocarbons in accordance with the Agency's regulations established under the American Innovation and Manufacturing Act of 2020. The American Innovation and Manufacturing Act directs the Environmental Protection Agency by October 1 of each calendar year to determine the quantity of production and consumption allowances for the following calendar year.

FOR FURTHER INFORMATION CONTACT: Andy Chang, U.S. Environmental Protection Agency, Stratospheric Protection Division, telephone number: 202-564-6658; email address: chang.andy@epa.gov. You may also visit EPA's website at <https://www.epa.gov/climate-hfcs-reduction> for further information.

SUPPLEMENTARY INFORMATION: Subsection (e)(2)(D)(i) of the American

Innovation and Manufacturing Act of 2020 (AIM Act) directs the Environmental Protection Agency (EPA) to determine, by October 1 of each calendar year, the quantity of allowances for the production and consumption of regulated substances that may be used for the following calendar year. EPA has codified the production and consumption baselines and phasedown schedules for regulated substances in 40 CFR 84.7. Under the phasedown schedule, for 2022, total production allowances may not exceed 344,299,157 metric tons of exchange value equivalent (MTEVe) and total consumption allowances may not exceed 273,498,315 MTEVe.

EPA's rulemaking titled *Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program under the American Innovation and Manufacturing Act*, signed September 23, 2021, describes the process by which EPA determines the number of allowances each entity is allocated. EPA has posted allowance allocations consistent with this process for calendar year 2022 allowances on its website at <https://www.epa.gov/climate-hfcs-reduction>. An allowance allocated under the AIM Act does not constitute a property right and is a limited authorization for the production or consumption of a regulated substance. For 2022, EPA has set aside 2.5 million MTEVe (MMTEVe) of allowances for production and 7.5 MMTEVe of allowances for consumption that it intends to allocate no later than March 31, 2022.

EPA has codified the procedure for calculating the application-specific allowance allocation in 40 CFR 84.13. These allowances are drawn from both the production and consumption allowance pools. EPA is issuing "application-specific allowances" to end users in six applications established by the AIM Act: Propellants in metered dose inhalers, defense sprays, structural composite preformed polyurethane foam for marine use and trailer use, etching of semiconductor material or wafers and the cleaning of chemical vapor deposition chambers within the semiconductor manufacturing sector, mission-critical military end uses, and onboard aerospace fire suppression. EPA has allocated 2022 application-specific allowances as shown in Table 1.

TABLE 1—APPLICATION-SPECIFIC ALLOWANCES FOR CALENDAR YEAR 2022

Entity	Application	Number of application-specific allowances issued (MTEVe) ¹
Boehringer Ingelheim	Metered Dose Inhalers	27,789.0
GlaxoSmithKline	Metered Dose Inhalers	414,448.2
Kindeva Drug Delivery	Metered Dose Inhalers	541,146.0
Lupin	Metered Dose Inhalers	30,224.8
Guardian Protective Devices	Defense Sprays	66,639.5
Safariland	Defense Sprays	19,404.6
Security Equipment Corporation	Defense Sprays	262,946.7
Shamrock Filling	Defense Sprays	138,559.0
UDAP Industries	Defense Sprays	116,029.3
Compsys	Structural Composite Foam	35,931.9
Wabash National Corporation	Structural Composite Foam	11,316.7
Analog Devices	Semiconductors	19,652.6
Applied Materials	Semiconductors	65,378.3
Broadcom	Semiconductors	4,232.3
Cree	Semiconductors	36,956.0
GE Global Research Center	Semiconductors	184.6
GlobalFoundries	Semiconductors	216,735.8
Intel Corporation	Semiconductors	679,471.5
Jireh Semiconductor	Semiconductors	5,628.6
Micron Technology	Semiconductors	54,598.3
Newport Fab DBA TowerJazz	Semiconductors	9,190.9
NXP Semiconductor	Semiconductors	56,910.6
Polar Semiconductor	Semiconductors	13,192.0
Qorvo Texas	Semiconductors	9,706.4
Samsung Austin Semiconductor	Semiconductors	260,269.0
Semiconductor Components Industries DBA ON Semiconductor.	Semiconductors	11,502.5
Texas Instruments	Semiconductors	73,345.6
Tower Semiconductor San Antonio	Semiconductors	9,836.6
WaferTech	Semiconductors	21,733.9
X-FAB Texas	Semiconductors	1,757.7
U.S. Department of Defense	Mission-critical Military	2,300,000.0
Raytheon Technologies	Onboard Aerospace Fire Suppression	44,105.4

¹ Numbers may not sum due to rounding.

EPA has codified the procedure for calculating the production allowance allocation in 40 CFR 84.9. EPA has allocated calendar year 2022 production allowances as shown in Table 2.

TABLE 2—PRODUCTION ALLOWANCES FOR CALENDAR YEAR 2022

Entity	Number of production allowances issued (MTEVe) ¹
Application-specific allowances ²	5,558,824.3
Set-aside ³	2,500,000.0
Arkema	40,555,947.3
Chemours	75,115,321.8
Honeywell International	170,413,409.6
Iofina Chemical	1,744.9
Mexichem Fluor DBA Koura	50,153,909.1

¹ Numbers may not sum due to rounding.

² See Table 1.

³ EPA intends to allocate set-aside allowances by March 31, 2022.

EPA has codified the procedure for calculating the consumption allowance allocation in 40 CFR 84.11. EPA has allocated calendar year 2022 consumption allowances as shown in Table 3.

TABLE 3—CONSUMPTION ALLOWANCES FOR CALENDAR YEAR 2022

Entity	Number of consumption allowances issued (MTEVe) ¹
Application-specific allowances ²	5,558,824.3
Set-aside ³	7,500,000.0
A-Gas	3,197,981.6
Advanced Specialty Gases	284,314.2
Air Liquide USA	496,782.6
Altair Partners	2,908,497.9
Arkema	30,966,544.3
Artsen	1,023,968.7
AutoZone Parts	2,477,946.6
AW Product Sales & Marketing	193,823.8
Bluon	33,342.5
Chemours	33,265,653.1
Combs Gas	1,283,403.1
ComStar International	372,752.5
Daikin America	3,109,990.8
Electronic Fluorocarbons	103,923.4
First Continental International	767,139.1
FluoroFusion Specialty Chemicals	2,543,583.9
GlaxoSmithKline	534,487.5
Harp USA	762,890.0
Honeywell International	82,208,205.2
Hudson Technologies	2,977,582.0
ICool USA	3,395,051.7
IGas Holdings	25,853,657.7
Iofina Chemical	1,260.5
Lenz Sales & Distribution	1,106,426.7
Linde	530,636.4
Mexichem Fluor DBA Koura	25,390,556.9
Mondy Global	317,589.6
National Refrigerants	19,737,372.2
Nature Gas Import and Export	816,751.0
Refrigerants, Inc.	26,457.8
RMS of Georgia	1,615,592.9
Showa Chemicals of America	73,209.0
Solvay Fluorides	1,098,594.2
Technical Chemical	970,724.9
Transocean Offshore Deepwater Drilling	16.7
Tulstar Products	731,537.3
Walmart	2,272,587.7
Waysmos USA	632,280.2
Weitron	6,316,123.6
Wilhelmsen Ships Service	40,250.9

¹ Numbers may not sum due to rounding.

² See Table 1.

³ EPA intends to allocate set-aside allowances by March 31, 2022.

Hans Christopher Grundler,

Director, Office of Atmospheric Programs.

[FR Doc. 2021-21951 Filed 10-6-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9073-01-R9]

Revision of Approved State Primacy Program for the State of Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of approval.

SUMMARY: Notice is hereby given that the State of Nevada (State) revised its

approved State primacy program under the federal Safe Drinking Water Act (SDWA) by adopting the federal Filter Backwash Recycling Rule. The Environmental Protection Agency (EPA) has determined that the State authorities implementing the program revision are no less stringent than the corresponding Federal regulations and that the State's request for a program revision meets applicable SDWA primacy requirements. Therefore, EPA approves Nevada's revision to its approved State primacy program. However, this revision does not become effective until the public process, describes below in this notice, is completed.

DATES: A request for a public hearing must be received or postmarked before November 8, 2021.

ADDRESSES: Documents relating to this determination are available online at <http://ndep.nv.gov/posts>. In addition, documents relating to this determination are available by appointment between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday, except official State or Federal holidays, at the following address: Nevada Department of Environmental Protection, Administration Office, 901 South Stewart Street, Suite 4001, Carson City, NV 89701. Please contact the Bureau of Safe Drinking Water at (775) 687-9521 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT:

Samantha Bishop, United States Environmental Protection Agency, Region 9, Drinking Water Section, via telephone at (415) 972-3411 or email address: bishop.samantha@epa.gov.

SUPPLEMENTARY INFORMATION:

Background. EPA approved Nevada's initial application for primary enforcement authority ("primacy") on February 27, 1978 (43 FR 8030). Since initial approval, EPA has approved various revisions to Nevada's primacy program. For the revision covered by this action, EPA published the Filter Backwash Recycling Rule on June 8, 2001 (66 FR 31086). EPA promulgated the Filter Backwash Recycling Rule to improve control of microbial pathogens while minimizing the public health risks of disinfectants and disinfection byproducts by reducing the opportunity for recycle practices to adversely affect the performance of drinking water treatment plants and preventing microbial contaminants from passing through treatment systems and into finished drinking water. EPA has determined that the Filter Backwash Recycling Rule requirements were adopted into the Nevada Administrative Code (NAC), Title 40 Chapter 445A, in a manner that Nevada's regulations are comparable to and no less stringent than the federal requirements. EPA has also determined that Nevada's program revision request meets all of the regulatory requirements for approval, as set forth in 40 CFR 142.12, including an acceptable side-by-side comparison of the Federal requirements to the corresponding State authorities, appropriate additional materials to meet the special primacy requirements of 40 CFR 142.16, an acceptable review of the requirements contained in 40 CFR 142.10 necessary for the State to retain primary enforcement responsibility, and a statement by the Nevada Attorney General certifying that Nevada's laws and regulations carrying out the program revision were duly adopted and are enforceable. The Attorney General's statement also affirms that there are no environmental audit privilege and immunity laws that would impact Nevada's ability to implement or enforce the Nevada laws and regulations pertaining to the program revision. Therefore, EPA approves this revision as part of Nevada's approved State primacy program. The Technical Support Document, which provides EPA's analysis of Nevada's program revision request for this approval, is available by submitting a request to the following email address: R9dw-program@epa.gov. Please note "Technical Support

Document" in the subject line of the email.

Public Process. Any interested party may request a public hearing on this determination. A request for a public hearing must be received or postmarked before November 8, 2021 and addressed to the Regional Administrator at the EPA Region 9, via the following email address: R9dw-program@epa.gov. Please note "State Primacy Rule Determination" in the subject line of the email. The Regional Administrator may deny frivolous or insubstantial requests for a hearing. If a substantial request for a public hearing is made before November 8, 2021, EPA Region 9 will hold a public hearing. Any request for a public hearing shall include the following information: 1. The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; 2. A brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; and 3. The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

If EPA does not receive a timely and appropriate request for a hearing and the Regional Administrator does not elect to hold a hearing on her own motion, EPA's approval shall become final and effective on November 8, 2021 and no further public notice will be issued.

Authority: Section 1413 of the Safe Drinking Water Act, as amended, 42 U.S.C. 300g-2 (1996), and 40 CFR part 142 of the National Primary Drinking Water Regulations.

Dated: September 28, 2021.

Deborah Jordan,

Acting Regional Administrator, EPA Region 9.

[FR Doc. 2021-21735 Filed 10-6-21; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1138; FR ID 50158]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 6, 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, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418-2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-1138.
Title: Sections 1.49 and 1.54, Forbearance Petition Filing Requirements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2 respondents; 2 responses.

Estimated Time per Response: 640 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 10, 151, 154(i), 154(j), 155(c), 160, 201 and 303(r) of the Communications Act of 1934.

Total Annual Burden: 1,280 hours.

Total Annual Cost: No cost.

Needs and Uses: Under section 10 of the Communications Act of 1934, as amended, telecommunications carriers may petition the Commission to forbear from applying to a telecommunications carrier any statutory provision or Commission regulation. When a carrier petitions the Commission for forbearance, section 10 requires the Commission to make three determinations with regard to the need for the challenged provision or regulation. If the Commission fails to act within one year (extended by three additional months, if necessary), the petition is “deemed granted” by operation of law. These determinations require complex, fact-intensive analysis, e.g., “whether forbearance from enforcing the provision or regulation will promote competitive market conditions.” Under the filing procedures, the Commission requires that petitions for forbearance must be “complete as filed” and explain in detail what must be included in the forbearance petition. The Commission also incorporates by reference its rule, 47 CFR 1.49, which states the Commission’s standard “specifications as to pleadings and documents.” Precise filing requirements are necessary because of section 10’s strict time limit for Commission action. Also, commenters must be able to clearly understand the scope of the petition in order to comment on it. Finally, standard filing procedures inform petitioners precisely what the Commission expects from them in order to make the statutory determinations that the statute requires.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021-21950 Filed 10-6-21; 8:45 am]

BILLING CODE 6712-01-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 October 22, 2021.

A. Federal Reserve Bank of San Francisco (Sebastian Astrada, Director, Applications) 101 Market Street, San Francisco, California 94105-1579:

1. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard;* to acquire additional voting shares of First American Financial Corporation, and thereby indirectly acquire voting shares of First American Trust, FSB, both of Santa Ana, California.

2. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard;* to acquire additional voting shares of First Hawaiian, Inc., and thereby indirectly acquire voting shares of First Hawaiian Bank, both of Honolulu, Hawaii.

3. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled*

investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard; to acquire additional voting shares of Pacific Premier Bancorp, Inc., and thereby indirectly acquire voting shares of Pacific Premier Bank, both of Irvine, California.

4. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard;* to acquire additional voting shares of PacWest Bancorp, and thereby indirectly acquire voting shares of Pacific Western Bank, both of Beverly Hills, California.

B. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Robin Saar and Candace Schubert, both of Shannon, Illinois, and Cassandre Rae Mlakar, Lake Carrol, Illinois;* to form the Saar Family Control Group, a group acting in concert to retain voting shares of Shannon Bancorp, Inc., and thereby indirectly retain voting shares of First State Bank Shannon-Polo, both of Shannon, Illinois.

C. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Charlotte Walden, as trustee of the George D. Walden Family Trust, both of Garden Plain, Kansas;* as members of the Walden Family Group, a group acting in concert, to retain voting shares of Garden Plain Bancshares, Inc., and thereby indirectly retain voting shares of Garden Plain State Bank, both of Wichita, Kansas.

In addition, Tyler Walden, Wichita, Kansas; Mary Conley, Savage, Minnesota; and the Kelli Walden Ventling Revocable Trust, Kelli Walden Ventling as trustee, both of Bluffton, South Carolina; to join the Walden Family Group, to retain voting shares of Garden Plain Bancshares, Inc., and thereby indirectly acquire voting shares of Garden Plain State Bank.

Board of Governors of the Federal Reserve System, October 4, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-21966 Filed 10-6-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0965]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 14 through 15, 2021, from 8:30 a.m. to 5 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by October 13, 2021. Comments received on or before October 12, 2021, will be provided to the committee. Comments received after October 12, 2021, and by October 13, 2021, will be taken into consideration by FDA.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following separate links on the days of the meeting:

Day 1: <https://youtu.be/Bh1shZ7Lkr0>.

Day 2: <https://youtu.be/c-H40GrvWz4>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0965. The docket will close on October 13, 2021. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

In the event that the meeting is canceled, FDA will continue to evaluate

any relevant applications, submissions, or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0965 for "Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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." FDA 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 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 the 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: Prabhakara Atreya or Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993-0002, 240-818-7798, via email at CBERVRBPAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link, or call the

advisory committee information line to learn about possible modifications before joining the meeting.

SUPPLEMENTARY INFORMATION: Consistent with FDA's regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the Vaccines and Related Biological Products Advisory Committee as soon as possible is warranted. This **Federal Register** notice could not be published 15 days prior to the date of the meeting due to recent requests to amend the Emergency Use Authorization (EUA) of the Moderna COVID-19 mRNA vaccine for the administration of a booster dose, following completion of the primary series, to individuals 18 years of age and older, and also the EUA of the Janssen Biotech Inc. COVID-19 vaccine for the administration of a booster dose, to individuals 18 years of age and older, and the need for prompt discussion of such requests given the COVID-19 pandemic.

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 14, 2021, under Topic 1, the committee will meet in open session to discuss the EUA of the Moderna COVID-19 mRNA vaccine for the administration of a booster dose, following completion of the primary series, to individuals 18 years of age and older. On October 15, 2021, under Topic II, the committee will meet in open session to discuss the EUA of the Janssen Biotech Inc. COVID-19 vaccine for the administration of a booster dose, to individuals 18 years of age and older.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/advisory-committee-calendar>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and

written submissions submitted to the Docket (see **ADDRESSES**) on or before October 12, 2021, will be provided to the committee. Comments received after October 12, 2021, and by October 13, 2021, will be taken into consideration by FDA. Oral presentations from the public will be scheduled approximately between 12:45 p.m. and 1:45 p.m. Eastern Time on October 14, 2021, and approximately between 11 a.m. and 12 noon Eastern Time on October 15, 2021. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before 6 p.m. October 8, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2021.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya or Kathleen Hayes (CBERVERBPAC@fda.hhs.gov) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 5, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-22037 Filed 10-5-21; 4:15 pm]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0271]

Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act" ("revised draft guidance"). This revised draft guidance, when finalized, will describe how FDA intends to apply certain provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to human drug products compounded by State-licensed pharmacies that are not outsourcing facilities and distributed for use within a hospital or health system. First, it addresses the requirement that compounding be based on the receipt of a valid prescription order for an identified individual patient. Second, it addresses the provision concerning compounded drug products that are essentially copies of a commercially available drug product. This draft guidance revises the draft guidance issued in 2016 entitled, "Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act" ("draft guidance"). FDA is revising the draft guidance to address stakeholder feedback and provide further clarification on policies regarding hospital and health system compounding. This revised draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the revised draft guidance by December 6, 2021 to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the revised draft guidance by December 6, 2021.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-0271 for "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revised draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the revised draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the revised draft guidance: Tracy Rupp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301-796-3100.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act." Pharmacies located within a hospital, or standalone pharmacies that are part of a health system, frequently provide compounded drug products for administration within the hospital or health system. Some of these compounders seek to compound under section 503A of the FD&C Act (21 U.S.C. 353a) and others have registered with FDA as outsourcing facilities and are subject to section 503B of the FD&C Act (21 U.S.C. 353b).

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements);
- Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
- Section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

This revised draft guidance proposes policies for FDA's application of certain provisions of section 503A of the FD&C Act to human drug products compounded by State-licensed pharmacies that are not outsourcing facilities and distributed for use within a hospital or health system. First, the revised draft guidance addresses the requirement that compounding be based on the receipt of a valid prescription order for an identified individual patient. Second, it addresses the provision concerning compounded drug products that are essentially copies of a commercially available drug product. This revised draft guidance does not apply to human drug products compounded by outsourcing facilities under section 503B of the FD&C Act, compounded drug products that are not distributed for use within a hospital or health system, or drug products compounded for use in animals.

In the **Federal Register** of April 18, 2016 (81 FR 22610), FDA announced the availability of a draft guidance for industry entitled, "Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act"

(“draft guidance”). The draft guidance proposed new policies for the application of section 503A of the FD&C Act to drug products compounded by licensed pharmacists or physicians in State-licensed hospital or health system pharmacies. In particular, the draft guidance described certain circumstances under which FDA generally would not intend to take action if a hospital or health system pharmacy distributed compounded drug products without first receiving a patient-specific prescription or order.

The comment period on the initial draft guidance ended on July 18, 2016. FDA received approximately 76 comments on the draft guidance. FDA is issuing a revised draft guidance with certain changes made in response to received comments or on its own initiative. For example, the prescription requirement enforcement policy described in the revised draft guidance does not consider whether the drug products are distributed only to healthcare facilities that are located within a 1-mile radius of the compounding pharmacy (“1-mile radius policy”). Instead, the Agency is proposing a two-part, risk-based compliance policy.

In addition, the revised draft guidance proposes new policies for hospital and health system pharmacies regarding the provision in section 503A of the FD&C Act which states that to qualify for the exemptions under section 503A of the FD&C Act, among other conditions, a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product.

FDA is issuing this revised draft guidance to address stakeholders’ feedback, reflect additional Agency consideration of the proposed policies, and enable the public to further review and comment before finalization.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on “Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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. We are consolidating the information collection in the revised draft guidance with the information collections and approvals under OMB control number 0910–0800.

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.

Human Drug Compounding Under Sections 503A and 503B the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Revision

This notice solicits comments on certain information collections found in the revised draft guidance entitled “Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act” (“revised draft guidance”). This guidance, when finalized, will support implementation of the copies provisions of the 1997 Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) discussed in section 503A of the FD&C Act, which were maintained by the 2013 Drug Quality and Security Act (DQSA) (Title I of Pub. L. 113–54).

For efficiency of Agency operations, we are revising OMB control number 0910–0800 to include information collections relating to the copies policies for hospital and health system pharmacies that are not outsourcing facilities, as proposed in the revised draft guidance document.

As proposed in section III.B of the revised draft guidance, among other conditions, we generally would not intend to take action against a hospital or health system pharmacy that is not an outsourcing facility for compounding a drug product regularly or in inordinate amounts that is essentially a copy of a commercially available drug product, if the compounded drug product is administered only to patients within the hospital or health system and the pharmacy obtains from the prescriber a statement that: (1) Specifies a change between the compounded drug product and the commercially available drug product; (2) indicates that the compounded drug product will be administered only to patients for whom the change produces a significant difference from the commercially available drug product; and (3) describes the intended patient population for the compounded drug product. In addition, the revised draft guidance specifies that the statement would be maintained in the hospital or health system pharmacy to address routine orders for patients for whom the change produces a significant difference, and a statement would be on file for each prescriber that covers each drug product that is compounded.

As provided in section III.B of the revised draft guidance, except for the policy proposed above regarding the documentation of a prescriber’s determination of significant difference, we propose to apply the policies described in the guidance, “Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act” (“503A copies guidance”) to drug products compounded by hospital and health system pharmacies that are not outsourcing facilities.

As described in section III.B.2 of the 503A copies guidance, and proposed in the revised draft guidance to apply to hospital and health system pharmacies, if a compounder intends to rely on a prescriber determination of significant difference to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription. If a prescription

does not make clear that the prescriber made the determination required by section 503A(b)(2) of the FD&C Act, or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described in the 503A copies guidance, and the date of the conversation with the prescriber should be included on the prescription.

With respect to the determination of significant difference described above, we estimate that, annually, a total of approximately 3,075 hospital or health system pharmacies (table 1) will obtain a prescriber determination of significant difference. This estimate represents approximately half of the hospitals in the United States, including those that are in health systems. Of these, we estimate that approximately half (1,538) will have hospital or health system pharmacies that will follow the policy in the revised draft guidance, obtaining a statement of significant difference for the intended patient population, and approximately half (1,537) will have hospital or health system pharmacies that will follow the policy with respect to prescriber determination of significant difference in the 503A copies guidance, documenting the notation on the individual patient prescription. This estimate assumes that most pharmacies in smaller hospitals and health systems will follow the policy in the 503A copies guidance because a prescriber determination of significant difference will not be routinely needed and can be most efficiently managed on a patient-by-patient basis. On the other hand, this estimate assumes that most pharmacies in larger hospitals and health systems will follow the policy in the revised draft guidance because the need for a prescriber determination of significant difference is more routinely necessary and, therefore, most efficiently managed with a statement of significant difference that is maintained in the hospital or health system pharmacy to address routine orders for patients for whom the change produces a significant difference.

We estimate that, annually, approximately 1,538 hospital or health system pharmacies following the policy in the revised draft guidance will obtain approximately 30 statements of significant difference for compounded drug products, for a total of approximately 46,140 statements (table 1, row 1). We estimate that the consultation between the hospital or health system pharmacy and the prescriber to obtain the statement of significant difference will require approximately 5 minutes per statement (table 1, row 1).

We estimate that, annually, approximately 1,537 hospital or health system pharmacies following the policy in the 503A copies guidance will consult a prescriber to determine whether the prescriber has made a determination that the compounded drug product has a change that produces a significant difference for a patient as compared to the comparable commercially available drug and that the compounders will document this determination on approximately 76,850 prescription orders for compounded drug products (table 1, row 2). We estimate that the consultation between the compounder and the prescriber and adding a notation to each prescription that does not already document this determination will take approximately 3 minutes per prescription order (table 1, row 2). The average burden per consultation and notation for pharmacies following the significant difference policy in the 503A copies guidance, compared to pharmacies following the significant difference policy in the revised draft guidance, is estimated to be less (3 minutes) because the significant difference determination described in the 503A copies policy is specific to one patient, whereas the statement of significant difference in the revised draft guidance describes the intended patient population.

In addition, as described in section III.B.3 of the 503A copies guidance, and proposed in the revised draft guidance to apply to hospital and health system pharmacies, if the drug product was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescription or a notation on the prescription should note that it was on the drug shortage list and note the date

the list was checked. We estimate that a total of approximately 4,613 hospital or health system pharmacies will document this information on approximately 922,600 prescription orders for compounded drug products (table 1, row 3). We estimate that checking FDA's drug shortage list and documenting this information will require approximately 2 minutes per prescription order (table 1, row 3).

With respect to maintaining records of the statement of significant difference proposed in section III.B of the revised draft guidance, we estimate that a total of approximately 1,538 hospital or health system pharmacies will maintain approximately 46,140 statements of significant difference (table 2, row 1). We estimate that maintaining the records will require approximately 2 minutes per record (table 2, row 1). With respect to maintaining records of the significant difference determination, as provided in section III.B.5 of the 503A copies guidance, we estimate that a total of approximately 1,537 hospital or health system pharmacies will maintain approximately 76,850 records (table 2, row 2). We estimate that maintaining records will require approximately 2 minutes per record (table 2, row 2).

Also with respect to maintenance of records, as described in section III.B.5 of the 503A copies guidance, and proposed in the revised draft guidance to apply to hospital and health system pharmacies, compounders under section 503A should maintain records of (1) the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and (2) the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products. We estimate that a total of approximately 3,075 hospital or health system pharmacies will maintain approximately 61,500 records of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products (table 2, row 3). We estimate that maintaining the records will require approximately 2 minutes per record (table 2, row 3).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the hospital or health system pharmacy and the prescriber to document the statement of significant difference (revised draft guidance).	1,538	30	46,140	.08 (5 minutes)	3,691
Consultation between the hospital or health system pharmacy and prescriber and the notation on the prescription documenting the prescriber's determination of significant difference (503A copies guidance).	1,537	50	76,850	.05 (3 minutes)	3,843
Hospital or health system pharmacy checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage (503A copies guidance).	4,613	200	922,600	.03 (2 minutes)	27,678
Total					35,212

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of the statement of significant difference (revised draft guidance)	1,538	30	46,140	.03 (2 minutes)	1,384
Records of documentation of significant difference (503A copies guidance)	1,537	50	76,850	.03 (2 minutes)	2,306
Records of frequency and number of prescriptions filled for compounded drug products that are essentially a copy (503A copies guidance).	3,075	20	61,500	.03 (2 minutes)	1,845
Total					5,535

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–21970 Filed 10–6–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for comments on the draft Department Strategic Plan for FY 2022–2026

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Planning and Evaluation, Health and Human Services.

ACTION: Request for comments on the draft HHS Strategic Plan FY 2022–2026.

SUMMARY: The Department of Health and Human Services (HHS) is seeking public comment on its draft Strategic Plan for Fiscal Years 2022–2026 through the Department of Health and Human Services website at www.hhs.gov/about/draft-strategic-plan/index.html.

DATES: Submit comments on or before November 7, 2021.

ADDRESSES: Written comments can be provided by email, Fax, or U.S. mail.

Email: HHSPlan@hhs.gov.

Fax: (202) 690–5882.

Mail: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Division of Strategic Planning, Attn: Strategic Plan Comments, 200 Independence Avenue SW, Room 434E, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

Margo Bailey, (202) 730–8504.

SUPPLEMENTARY INFORMATION: The draft Department of Health and Human Services Strategic Plan FY 2022–2026 is provided as part of the strategic planning process under the Government Performance and Results Modernization Act of 2010 (GPRA–MA)(Pub. L. 111–352) to ensure that Agency stakeholders are given an opportunity to comment on this plan.

This document articulates how the Department will achieve its mission through five strategic goals. These five strategic goals are (1) Protect and Strengthen Equitable Access to High Quality and Affordable Health Care, (2) Safeguard and Improve National and Global Health Conditions and Outcomes, (3) Strengthen Social Well-being, Equity, and Economic Resilience, (4) Restore Trust and Accelerate Advancements in Science and Research for All, and (5) Advance Strategic Management to Build Trust, Transparency, and Accountability. Each goal is supported by objectives and strategies.

The strategic planning consultation process is an opportunity for the Department to refine and strengthen the HHS Strategic Plan FY 2022–2026. We look forward to receiving your comments by November 7, 2021. The text of the draft HHS Strategic Plan FY 2022–2026 is available through the Department of Health and Human Services website at www.hhs.gov/about/draft-strategic-plan/index.html. For comparison purposes, the current HHS Strategic Plan FY 2018–2022 can be viewed at <https://www.hhs.gov/about/strategic-plan/index.html>.

For those who may not have internet access, a hard copy can be requested from the contact point, Margo Bailey, (202) 730–8504.

Dated: September 29, 2021.

Rebecca Haffajee,

Acting Assistant Secretary for Planning and Evaluation (ASPE), Principal Deputy, ASPE.

[FR Doc. 2021–21939 Filed 10–5–21; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Public Comments on the Development of the 2021–2022 IACC Strategic Plan for Autism Spectrum Disorder (ASD)

SUMMARY: On behalf of the Interagency Autism Coordinating Committee (IACC), the National Institute of Mental Health (NIMH) Office of Autism Research

Coordination (OARC) is seeking public comments to assist the IACC in identifying priorities for the 2021–2022 update of the IACC Strategic Plan for Autism Spectrum Disorder (ASD) as required by the Autism Collaboration, Accountability, Research, Education and Support (CARES) Act of 2019. The IACC is requesting public comments on research, services, and policy issues related to the seven topics addressed by the IACC Strategic Plan: Screening and Diagnosis, Biology, Risk Factors, Treatments and Interventions, Services, Lifespan Issues, and Infrastructure and Surveillance. The IACC is also requesting information on two additional issues related to autism described in two supplemental questions that are included in this Request for Public Comment.

DATES: Responses to this notice are voluntary and the public comment period will be open from October 1, 2021–November 30, 2021.

ADDRESSES: All comments must be submitted electronically via the web-based form at: <https://iacc.hhs.gov/meetings/public-comments/requests-for-information/2021/strategic-plan.shtml>.

FOR FURTHER INFORMATION CONTACT: Specific questions about this Request for Public Comment should be directed to: Rebecca Martin by phone at (301) 435–0886 or email at iaccpublicinquiries@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The IACC <http://www.iacc.hhs.gov/> is a federal advisory committee composed of federal and public members that provides advice to the Secretary of Health and Human Services on autism spectrum disorder. The Committee is authorized under the Autism CARES Act of 2019, Public Law 116–60. The law requires that the IACC develop a Strategic Plan for autism research and update the Plan annually. The current IACC Strategic Plan can be viewed at: <https://iacc.hhs.gov/publications/strategic-plan/2019/>. The IACC last provided an update on the progress of the Strategic Plan in 2019, after which the committee went out of session as a new committee was being appointed. The IACC reconvened in July 2021 and is now developing a new update of the IACC Strategic Plan.

The IACC Strategic Plan chapters are organized around seven topic areas that are related to community-focused questions:

- Question 1. How Can I Recognize the Signs of ASD, and Why is Early Detection So Important? (Topic: Screening and Diagnosis)
- Question 2. What Is the Biology Underlying ASD? (Topic: Biology)

- Question 3. What Causes ASD, and Can Disabling Aspects of ASD be Prevented or Preempted? (Topic: Risk Factors)
- Question 4. Which Treatments and Interventions Will Help? (Topic: Treatments and Interventions)
- Question 5. What Kinds of Services and Supports Are Needed to Maximize Quality of Life for People on the Autism Spectrum? (Topic: Services)
- Question 6. How Can We Meet the Needs of People with ASD as They Progress into and through Adulthood? (Topic: Lifespan Issues)
- Question 7. How Do We Continue to Build, Expand, and Enhance the Infrastructure System to Meet the Needs of the ASD Community? (Topic: Infrastructure and Surveillance)

The Committee also seeks public comment related to the two following questions:

- Supplemental Question 1. What are important issues for the IACC to consider with regard to the impact of the COVID–19 pandemic on the autism community?
- Supplemental Question 2. What are important issues for the IACC to consider with regard to the needs of underserved populations within the autism community, including racial and ethnic minorities, economically disadvantaged communities, and rural populations?

Submission Information. For each topic/question in the Request for Public Comment, commenters may provide input on what they consider to be the most important research, services, and policy issues and remaining gaps in the subject area covered by that Question.

Please note that the web form will accept a maximum of 1,500 characters (including letters, numbers, punctuation, etc.) per topic area. A valid email address is required for submission, and only one submission per email address will be accepted. If duplicate submissions are received (*i.e.*, form letters), only one example of such a submission will be included in the final set of comments.

The information that commenters provide will become part of the public record; as such, please do not include any personally identifiable or confidential information in the comments. The web form will provide the option of submitting responses anonymously, or the choice to include a name and/or organization associated with the comment. Comments are subject to redaction in accordance with federal policies and the IACC's public

comment guidelines and privacy policy. To view the IACC's public comment guidelines and privacy policy, visit: <https://iacc.hhs.gov/meetings/public-comments/guidelines/>. All comments or summaries of comments received will be made publicly available on the IACC website www.iacc.hhs.gov within 90 days of the closing deadline for this notice. Email addresses associated with comments will not be included as part of the public disclosure. After the closing deadline, responses cannot be edited or withdrawn. No basis for claims against the U.S. Government shall arise as a result of a response to this request for information or from the Government's use of such information.

Instructions. All comments must be submitted through the web form at <https://iacc.hhs.gov/meetings/public-comments/requests-for-information/2021/strategic-plan.shtml>. Individuals submitting comments will receive an onscreen confirmation acknowledging receipt of the comment, but commenters will not receive individualized feedback or responses from the IACC. Only one comment per email address will be accepted, and if duplicate comments are received, only one example will be provided to the IACC.

Dated: September 30, 2021.

Susan A. Daniels,

Director, Office of Autism Research Coordination, National Institute of Mental Health.

[FR Doc. 2021–21883 Filed 10–6–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Ovarian Physiology.

Date: November 1, 2021.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6701 Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Luis E. Dettin, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, 301-827-8231, luis.dettin@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: October 4, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-21903 Filed 10-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Population Sciences Study Section.

Date: October 18, 2021.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2121B,

Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Rm. 2121B, Bethesda, MD 20892, (301) 451-4989, crobbs@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Archiving and Documenting Child Health and Human Development Data Sets.

Date: October 18, 2021.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2121B, Bethesda, MD 20892, 301-451-4989, crobbs@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: October 4, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-21899 Filed 10-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act. To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276-0361.

Project: State Opioid Response (SOR)/ Tribal Opioid Response (TOR) Program Instrument (OMB No. 0930-0384)—Revision

SAMHSA is requesting approval to modify its existing CSAT SOR/TOR Program Instrument by (1) collapsing the original three questions into two questions for clarity and (2) adding ten questions in order to collect information on Congressionally mandated and programmatic activities, and comply with reporting requirements. The program-level information is collected quarterly and entered and stored in SAMHSA's Performance Accountability and Reporting System, which is a real-time, performance management system that captures information on the substance use prevention and treatment and mental health services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 reporting requirements that quantify the effects and accomplishments of its discretionary grant programs.

The SOR/TOR programs were first authorized under Title II Division H of the Consolidated Appropriations Act, 2018, Public Law 115-141. SAMHSA anticipates 159 recipients (states, territories, and tribal entities) will participate in these grant programs. Grantee-level data will include information related to: Reported overdose reversals; the purchase and distribution of naloxone; training in the administration of naloxone; implementation of prevention and education activities; outreach activities for underserved communities; and the purchase and distribution of fentanyl test strips. This grantee-level information will be collected quarterly.

The revisions to the tool will enable SAMHSA to better assess grantee accountability and performance on the required education and prevention activities for the SOR/TOR programs. SAMHSA will also use the data collected through the revised tool to implement recommendations resulting from the GAO study, "Drug Misuse: Agencies Have Not Fully Identified How Grants That Can Support Drug Prevention Education Programs Contribute to National Goals (GAO-21-96).¹ Finally, the revisions will assist SAMHSA in providing comprehensive

¹ United States Government Accountability Office. (2020, November). Drug Misuse: Agencies Have Not Fully Identified How Grants That Can Support Drug Prevention Education Programs Contribute to National Goals. <https://www.gao.gov/assets/gao-21-96.pdf>.

data on the full range of required activities to inform Congressionally mandated reports for the SOR program. CSAT anticipates that the time required to collect and report the

program-level information is approximately 18 minutes per response. Since the submission of the original OMB package, there has been a reduction in the number of respondents.

The estimated burden associated with the program-level instrument includes an adjustment to reflect the current number of grantees.

TABLE 1—ESTIMATE OF ANNUALIZED HOUR BURDEN FOR SOR/TOR GRANTEES

SAMHSA data collection	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours	Hourly wage ¹	Total wage cost
Grantee-Level Instrument	159	4	636	.30	190.80	\$24.78	\$4,728.02
CSAT Total	159	4	636	.30	190.80	24.78	4,728.02

¹ The hourly wage estimate is \$24.78 based on the Occupational Employment and Wages, Mean Hourly Wage Rate for 21–1018 Substance Abuse, Behavioral Disorder, and Mental Health Counselors = \$24.78/hr. as of May 2020 (<https://www.bls.gov/oes/current/oes211018.htm> Accessed on May 4, 2021.).

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.

Carlos Graham,
Reports Clearance Officer.
 [FR Doc. 2021–21965 Filed 10–6–21; 8:45 am]
BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 (OMB No. 0930–0206) and Opioid Treatment Programs (OTPs)—Extension

42 CFR part 8 establishes a certification program managed by SAMHSA’s Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. “Certification” is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168),

which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient’s medical examination when admitted to treatment, a patient’s history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient’s dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient’s clinic attendance, and documentation of physiologic dependence.

The table that follows summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are no changes being made to the forms.

Form	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
Estimated Annual Reporting Requirement Burden for Accreditation Bodies					
SMA–163	54	26.055	1,407	0.28	394
Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs					
SMA–162	651.33	17.976	11,708.91
SMA–168	1,302.67	17.977	23,418.09
Subtotal	1954	17.977	35,127	0.08	2902
Total	36,534	3296

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.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2021–21963 Filed 10–6–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7034–N–56]

7-Day Notice of Emergency Approval of an Information Collection: Extension of Time and Required Disclosures for Notification of Nonpayment of Rent Information Collection Request; OMB Control Number: 2502–0178

AGENCY: Office of the Chief Information Officer, Department of Housing and Urban Development (HUD).

ACTION: Emergency notice.

SUMMARY: In accordance with the Paperwork Reduction Act, HUD has requested from the Office of Management and Budget (OMB) emergency approval of the information collection described in this notice. HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 7 days of public comment.

DATES: *Comments due date:* October 14, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 7 days of publication of this notice to OIRA_submission@omb.eop.gov or 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.

FOR FURTHER INFORMATION CONTACT:

Collette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Ms. Pollard at Colette.Pollard@hud.gov or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Extension of Time and Required Disclosures for Notification of Nonpayment of Rent Information Collection Request

OMB Approval Numbers:
2577–0006 Public Housing Agency (PHA) Lease Requirements, Recordkeeping Requirements.

2502–0178 Management Reviews of Multifamily Housing Programs.

Type of Request: Revisions of existing collection 2577–0006, and 2502–0178.

Form Number(s): N/A

Description of the need for the information and proposed use: The change to the existing information collection requests (ICRs) will provide for the burden on public housing agencies and multifamily owners of properties that receive project-based rental assistance to provide information to their tenants about Federal funding available related to a national emergency. Elsewhere in this issue of the **Federal Register**, HUD is publishing an interim final rule entitled “Extension of Time and Required Disclosures for

Notification of Nonpayment of Rent” (FR–6286–F–01), which provides the Secretary, upon making the requisite findings and providing the requisite notice, may require housing providers participating in public housing and properties with project-based rental assistance (PBRA) to provide tenants facing eviction for non-payment of rent with notification of and information about the opportunity to secure emergency funding and additional time to secure such funding prior to eviction. This Paperwork Reduction Act (PRA) amends the existing collections covering notifications for tenants for failure to pay rent in both the public housing collection, OMB No. 2577–0006, and the PBRA collection, OMB No. 2502–0178, to account for the additional burden of providing the additional notice to tenants in advance of an eviction with information about the opportunity to secure emergency funding and additional time to secure such funding prior to eviction.

HUD estimates a total of 217,000 households will be helped from receiving this eviction notification. HUD distributes that number amongst the programs’ collections and number of PHAs and multifamily owners. HUD anticipates the burden on the PHA and owners to be updating their standard lease termination notice with the new information, either by incorporating it into the notice, where applicable, or by providing it as a separate addendum. Providing the notice would not create additional burdens, as PHA and owners are already required to provide a notification when a household fails to pay rent. Thus, HUD anticipates minimal additional costs for this notice requirement. Finally, for the public housing program only, the rule requires PHAs to inform all public housing tenants that the extended timeframe for notification of lease termination due to nonpayment of rent is in effect, and that families will be provided information on available funding in that 30-day notification.+

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
2577–0006 ...	2,838	1	2,838	.25	709.5	\$18.28	12,969.66
2502–0178 ...	27,127	1	27,127	.25	6,781.75	32.60	221,085.05
Total	29,965	1	29,965	.25	7,491.257,491.25	XX	234,054.71

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected

parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

(5) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or the forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

*Department Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 2021-21961 Filed 10-6-21; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[2221A2100DD/AAKC001030/
A0A501010.999900 253G; OMB Control
Number 1076-0122]

**Agency Information Collection
Activities; Submission to the Office of
Management and Budget for Review
and Approval; Data Elements for
Student Enrollment in Bureau-Funded
Schools**

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice of information collection;
request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Education (BIE) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before November 8, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://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. Please provide a copy of your comments to Cole G. Bowers, NASIS Specialist, Chief Academic Office, Bureau of Indian Education, U.S. Department of the Interior, 1849 C Street NW, MIB-3609, Washington, DC 20240; or by email to cole.bowers@bie.edu. Please reference OMB Control Number 1076-0122 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mr. Cole Bowers at phone: (202) 208-2977 or cole.bowers@bie.edu. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1-800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on June 15, 2021 (86 FR 31728). No comments were received.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. 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 BIE is requesting renewal of OMB approval for the admission forms for the Student Enrollment Application in Bureau-funded Schools. School registrars collect information on this form to determine the student's eligibility for enrollment in a Bureau-funded school, and if eligible, is shared with appropriate school officials to identify the student's base and supplemental educational and/or residential program needs. The BIE compiles the information into a national database to facilitate budget requests and the allocation of congressionally appropriated funds.

Proposed Revisions to This Information Collection

We are proposing minor revisions to the format, content, and layout of the form.

Title of Collection: Data Elements for Student Enrollment in Bureau-Funded Schools.

OMB Control Number: 1076-0122.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Contract and Grant schools, and Bureau-funded schools.

Total Estimated Number of Annual Respondents: 48,000 per year, on average.

Total Estimated Number of Annual Responses: 48,000 per year, on average.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 12,000 hours.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: Once per year.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2021-21936 Filed 10-6-21; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs**

[2221A2100DD/AAK001030/
AOA501010.999900 253G; OMB Control
Number 1076-0104]

**Agency Information Collection
Activities; Submission to the Office of
Management and Budget for Review
and Approval; Federal
Acknowledgment as an Indian Tribe,
25 CFR 83**

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice of information collection;
request for comment.

SUMMARY: In accordance with the
Paperwork Reduction Act of 1995, we,
the Assistant Secretary—Indian Affairs
(AS-IA) are proposing to renew an
information collection with revisions.

DATES: Interested persons are invited to
submit comments on or before
November 8, 2021.

ADDRESSES: Send written comments on
this information collection request (ICR)
to the Office of Management and
Budget's Desk Officer for the
Department of the Interior by email at
OIRA_Submission@omb.eop.gov; or via
facsimile to (202) 395-5806. Please
provide a copy of your comments to R.
Lee Fleming, Director, Office of Federal
Acknowledgment, Assistant Secretary—
Indian Affairs, 1849 C Street NW, MS-
4071 MIB, Washington, DC 20240;
facsimile: (202) 219-3008; email:
Lee.Fleming@bia.gov. Please reference
OMB Control Number 1076-0104 in the
subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To
request additional information about
this ICR, contact R. Lee Fleming, (202)
513-7650. You may also view the ICR
at [http://www.reginfo.gov/public/do/
PRAMain](http://www.reginfo.gov/public/do/PRAMain).

SUPPLEMENTARY INFORMATION: In
accordance with the Paperwork
Reduction Act of 1995, we provide the
general public and other Federal
agencies with an opportunity to
comment on new, proposed, revised,
and continuing collections of
information. This helps us assess the
impact of our information collection
requirements and minimize the public's
reporting burden. It also helps the
public understand our information
collection requirements and provides
the requested data in the desired format.

A **Federal Register** notice with a 60-
day public comment period soliciting
comments on this collection of
information was published on May 20,

2021 (86 FR 27464). No comments were
received.

We are again soliciting comments on
the proposed ICR that is described
below. We are especially interested in
public comment addressing the
following issues: (1) Is the collection
necessary to the proper functions of the
AS-IA; (2) will this information be
processed and used in a timely manner;
(3) is the estimate of burden accurate;
(4) how might the AS-IA enhance the
quality, utility, and clarity of the
information to be collected; and (5) how
might the AS-IA minimize the burden
of this collection on the respondents,
including through the use of
information technology.

Comments that you submit in
response to this notice are a matter of
public record. 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: Submission of this
information allows the Office of Federal
Acknowledgment (OFA), within the
Office of the Assistant Secretary—
Indian Affairs, to review groups'
documented petitions for the Federal
acknowledgment as an Indian tribe. The
acknowledgment regulations at 25 CFR
83 contain seven criteria that
unrecognized groups seeking Federal
acknowledgment as Indian tribes must
demonstrate that they meet. Information
collected from petitioning groups under
these regulations provide
anthropological, genealogical, and
historical data used by the AS-IA to
establish whether a petitioning group
has the characteristics necessary to be
acknowledged as a continuously
existing Indian tribe. Federal
acknowledgment establishes a
government-to-government relationship
with the United States. Respondents are
not required to retain copies of the
information submitted to OFA but will
probably maintain copies for their own
use; therefore, there is no recordkeeping
requirement included in this
information collection.

**Proposed Revisions to This Information
Collection**

We are no longer planning to revise
this information collection to include
collections of information related to
petitions for Federal acknowledgment

under 25 CFR part 82, for entities in
Alaska that were not recognized as
bands or Tribes before 1936, as stated in
the proposed rule published in the
Federal Register of January 2, 2020 (85
FR 26902) and May 5, 2020 (85 FR
26902).

Title of Collection: Federal
Acknowledgment as an Indian Tribe, 25
CFR 83.

OMB Control Number: 1076-0104.

Form Number: BIA-8304, BIA-8305,
and BIA-8306.

Type of Review: Revision of a
currently approved collection.

Respondents/Affected Public: Groups
petitioning for Federal acknowledgment
as Indian Tribes.

**Total Estimated Number of Annual
Respondents:** 1 per year, on average.

**Total Estimated Number of Annual
Responses:** 1 per year, on average.

**Estimated Completion Time per
Response:** 1,516 hours, on average.

**Total Estimated Number of Annual
Burden Hours:** 1,516 hours.

Respondent's Obligation: Required to
Obtain a Benefit.

Frequency of Collection: Once.

**Total Estimated Annual Nonhour
Burden Cost:** \$2,100,000.

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.*)

Elizabeth K. Appel,

*Director, Office of Regulatory Affairs and
Collaborative Action—Indian Affairs.*

[FR Doc. 2021-21940 Filed 10-6-21; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[LLNM931000.L1440000.BJ0000
212L1109AF]

**Notice of Filing of Plats of Survey; New
Mexico**

AGENCY: Bureau of Land Management,
Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the
following described lands are scheduled
to be officially filed in the Bureau of
Land Management (BLM), New Mexico
State Office, Santa Fe, New Mexico, 30
days after the date of this publication.
The surveys announced in this notice
are necessary for the management of
lands administered by the agency
indicated.

DATES: Unless there are protests of this action, the plats described in this notice will be filed on November 8, 2021.

ADDRESSES: These plats will be available for inspection in the New Mexico State Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico 85004-4427. Protests of a survey should be sent to the New Mexico State Director at the above address.

FOR FURTHER INFORMATION CONTACT: Michael J. Purtee, Chief Cadastral Surveyor; (505) 761-8903; mpurtee@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

New Mexico Principal Meridian, New Mexico:

The plat, representing the dependent resurvey of a portion of the subdivisional lines within Township 16 North, Range 11 East, and certain mineral surveys in Townships 16 and 17 North, Range 11 East, accepted February 1, 2021, for Group 1191, New Mexico. This plat was prepared at the request of the U.S. Department of Agriculture, Santa Fe National Forest, Region 3.

The plat, representing the dependent resurvey of a tract of land in Township 22 North, Range 14 East, accepted October 22, 2020, for Group 1199, New Mexico. This plat was prepared at the request of the U.S. Department of Agriculture, Carson National Forest, Region 3.

The plat, representing the dependent resurvey, survey, and metes-and-bounds survey of a tract of land within Township 12 North, Range 11 West, accepted March 15, 2021, for Group 1202, New Mexico. This plat was prepared at the request of the Bureau of Land Management, Rio Puerco District Office.

The plat, representing the dependent resurvey and survey of tracts of land in Township 26 South, Range 29 East, accepted March 25, 2021, for Group 1205, New Mexico. This plat was prepared at the request of the Bureau of Land Management, New Mexico State Office, Lands and Minerals Department.

A person or party who wishes to protest any of these surveys must file a written notice of protest within 30 calendar days from the date of this publication at the address listed in the **ADDRESSES** section of this notice. A

statement of reasons for a protest may be filed with the notice of protest or the statement of reasons must be filed with the State Director for New Mexico within 30 days after the protest is filed. A notice of protest is considered filed on the date it is received by the State Director for New Mexico during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. Any notice of protest filed after the scheduled date of official filing will be untimely and will not be considered. A statement of reasons for the protest may be filed with the notice of protest and must be filed within 30 calendar days after the protest is filed. If a notice of protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the next business day after all protests have been dismissed or otherwise resolved.

Before including your address, or other personal information in your protest, please be aware that your entire protest, 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.

Authority: 43 U.S.C. Chap. 3.

Michael J. Purtee,

Chief Cadastral Surveyor, BLM New Mexico.

[FR Doc. 2021-21964 Filed 10-6-21; 8:45 am]

BILLING CODE 4310-FB-P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR-2011-0019; DS63644000 DRT000000.CH7000 223D1113RT, OMB Control Number 1012-0001]

Agency Information Collection Activities; Accounts Receivable Confirmations Reporting

AGENCY: Office of Natural Resources Revenue (“ONRR”), Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (“PRA”), ONRR is proposing to renew an information collection. Through this Information Collection Request (“ICR”), ONRR seeks renewed authority to collect information from royalty payors to verify a small number of ONRR accounts receivable randomly selected

by the Office of Inspector General (“OIG”) for audit.

DATES: Interested persons are invited to submit comments on or before November 8, 2021.

ADDRESSES: All comment submissions must (1) reference “OMB Control Number 1012-0001” in the subject line; (2) be sent to ONRR before the close of the comment period listed under **DATES**; and (3) be sent through one of the following two methods:

- *Electronically via the Federal eRulemaking Portal:* Please visit <https://www.regulations.gov>. In the Search Box, enter the Docket ID Number for this ICR renewal (“ONRR-2011-0019”) to locate the document and click the “Comment Now!” button. Follow the prompts to submit your comment prior to the close of the comment period.

- *Email Submissions:* Please email your comments to ONRR_RegulationsMailbox@onrr.gov with the Control Number (“OMB Control Number 1012-0001”) listed in the subject line of your email. Email submissions must be postmarked on or before the close of the comment period.

Docket: To access the docket to view ICR publications in the **Federal Register**, go to <https://www.regulations.gov> and search “ONRR-2011-0019”. The docket will display renewal notices recently published in the **Federal Register**, publications associated with prior renewals, and applicable public comments received for this ICR.

OMB ICR Data: OMB also maintains information on ICR renewals and approvals. You may access this information at <https://www.reginfo.gov/public/do/PRASearch>. Please use the following instructions: Under the “OMB Control Number” heading enter “1012-0001” and click the “Search” button located at the bottom of the page. To view the ICR renewal or OMB approval status, click on the latest entry (based on the most recent date). On the “View ICR—OIRA Conclusion” page, check the box next to “All” to display all available ICR information provided by OMB.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, please contact Ms. Jennifer Dougherty, Financial Management, Revenue, Reporting, and Compliance Management, ONRR by email at Jennifer.Dougherty@onrr.gov or by telephone at (303) 231-3563. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1-800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: Pursuant to the PRA, 44 U.S.C. 3501, *et seq.*, and

5 CFR 1320.5, all information collections as defined in 5 CFR 1320.3, require approval by OMB. ONRR may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of ONRR's continuing effort to reduce paperwork and respondent burdens, ONRR is inviting the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information in accordance with the PRA and 5 CFR 1320.8(d)(1). This helps ONRR assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand ONRR's information collection requirements and provide the requested data in the desired format.

ONRR is especially interested in public comments addressing the following:

(1) 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;

(2) The accuracy of ONRR's 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.

ONRR published a notice, with a 60-day public comment period soliciting comment of this collection of information, in the **Federal Register** on April 21, 2021 (86 FR 20710). ONRR received no comments from companies regarding the published 60-day **Federal Register** notice.

Comments that you submit in response to this 30-day notice are a matter of public record. ONRR will include or summarize each comment in its 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 ONRR in your comment to withhold information from public review, ONRR cannot guarantee that it will be able to do so.

Abstract: (a) General Information: The Federal Oil and Gas Royalty Management Act of 1982 ("FOGRMA") directs the Secretary of the Interior ("Secretary") to maintain a comprehensive inspection, collection, and fiscal and production accounting and auditing system that: (1) Accurately determines mineral royalties, interest, and other payments owed, (2) collects and accounts for such amounts in a timely manner, and (3) disburses the funds collected. See 30 U.S.C. 1701 and 1711. ONRR performs these mineral revenue management responsibilities for the Secretary. See Secretarial Order No. 3306. Royalty payors submit royalty reports to ONRR on a monthly basis by submitting form ONRR-2014 (Report of Sales and Royalty Remittance reported in OMB Control Number 1012-0004), and form ONRR-4430 (Solid Minerals Production and Royalty Report reported in OMB Control Number 1012-0010). These forms result in accounts receivables and capture most of the mineral revenues that ONRR collects.

(b) Information Collections: Every year, under the Chief Financial Officers Act of 1990 ("CFO Act"), the OIG or its agent audits the accounts receivable portions of the Department of the Interior's financial statements, which includes ONRR accounts receivable. As part of the audit, the OIG or its agent randomly selects a sample of ONRR accounts receivable. For each one selected, ONRR generates an accounts receivable confirmation letter to the royalty payor to obtain third-party confirmation of the validity of the financial record for the audit. In order to meet the CFO Act's requirements, the letter must be on ONRR letterhead and the Deputy Director for ONRR, or his or her designee, must sign the letter. The letter requests a response by a specified date to verify: (1) Customer identification; (2) royalty invoice number; (3) payor assigned document number; (4) date of ONRR's receipt; (5) original amount the payor reported; and (6) remaining balance due to ONRR. The OIG or its agent mails the letter to the payor and instructs it to respond directly to the OIG or its agent. The information provided helps ensure that ONRR's financial records are accurate.

Title of Collections: Accounts Receivable Confirmations Reporting.

OMB Control Number: 1012-0001.

Form(s) Number: None.

Type of Review: Extension of a currently approved collection.

Respondent/Affected Public: Businesses.

Total Estimated Number of Annual Respondents: 24 randomly-selected

mineral payors from Federal and Indian lands and the Outer Continental Shelf.

Total Estimated Number of Annual Responses: 24.

Estimated Completion Time per Response: ONRR estimates that each response will take 15 minutes for the payor to complete.

Total Estimated Number of Annual Burden Hours: 6 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annual.

Total Estimated Annual Non-hour Burden Cost: ONRR did not identify any "non-hour cost" burden associated with this collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501 *et seq.*)

Kimbra G. Davis,

Director, Office of Natural Resources Revenue.

[FR Doc. 2021-21893 Filed 10-6-21; 8:45 am]

BILLING CODE 4335-30-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-905]

Importer of Controlled Substances Application: AndersonBrecon, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AndersonBrecon, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 8, 2021. Such persons may also file a written request for a hearing on the application on or before November 8, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All request for a hearing should also be sent to: (1) Drug

Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on May 19, 2021, AndersonBrecon, Inc., 4545 Assembly Drive, Rockford, Illinois 61109, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols ...	7370	I

The company plans to import the listed controlled substance for clinical trials only. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Brian S. Besser,
Acting Assistant Administrator.
[FR Doc. 2021-21876 Filed 10-6-21; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-906]

Importer of Controlled Substances Application: Caligor Coghlan Pharma Services

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Caligor Coghlan Pharma Services has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 8, 2021. Such persons may also file a written request for a hearing on the application on or before November 8, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement

Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on August 16, 2021, Caligor Coghlan Pharma Services, 1500 Business Park Drive, Unit B, Bastrop, Texas 78602, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tapentadol	9780	II

The company plans to import the listed controlled substance in finished dosage form to be used in pediatric clinical trials. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Brian S. Besser,
Acting Assistant Administrator.
[FR Doc. 2021-21878 Filed 10-6-21; 8:45 am]
BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-907]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: New Mexico Top Organics-Ultra Health

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered

to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before December 6, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW 8701 Morrisette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No—DEA—907 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA-registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and

reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on August 27, 2021, New Mexico Top Organics-Ultra Health, 225 Camino Don Tomas, Bernalillo, New Mexico 87004, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2021-21879 Filed 10-6-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 04-21]

Sunshine Act Meetings

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

TIME AND DATE: Thursday, October 21, 2021, at 1:00 p.m. EST.

PLACE: This meeting will be held by teleconference. There will be no physical meeting place.

STATUS: Open. Members of the public who wish to observe the meeting via teleconference should contact Patricia M. Hall, Foreign Claims Settlement Commission, Tele: (202) 616-6975, two business days in advance of the meeting. Individuals will be given call-in information upon notice of attendance to the Commission.

MATTERS TO BE CONSIDERED: 1:00 p.m.—Issuance of Proposed Decisions under the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114-328.

CONTACT PERSON FOR MORE INFORMATION: Requests for information, advance notices of intention to observe an open meeting, and requests for teleconference dial-in information may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 441 G St. NW,

Room 6234, Washington, DC 20579. Telephone: (202) 616-6975.

Jeremy R. LaFrancois,

Chief Administrative Counsel.

[FR Doc. 2021-22009 Filed 10-5-21; 11:15 am]

BILLING CODE 4410-BA-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Clean Air Act; The Comprehensive Environmental Response, Compensation, and Liability Act; and The Emergency Planning and Community Right-To-Know Act

On September 30, 2021, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Louisiana in the lawsuit entitled *United States et al. v. Firestone Polymers, LLC*, Case No. 2:21-cv-03464.

The proposed Consent Decree resolves claims asserted in the Complaint filed in the action that Firestone Polymers, LLC (“Defendant”) violated the Clean Air Act (“CAA”), and other federal statutes, and related Louisiana state air pollution control laws applicable to the synthetic rubber production facility located in Sulphur, Calcasieu Parish near Lake Charles, Louisiana. The Complaint alleges that the CAA violations resulted in the emission of illegal pollutants, including nitrogen oxides, carbon monoxide, volatile organic compounds, particulate matter, and sulfur dioxide, and hazardous air pollutants. Other claims involve alleged violations of the Comprehensive Environmental Response, Compensation, and Liability Act, the Emergency Planning and Community Right-to-Know Act, and Louisiana state air pollution control requirements governed by the Louisiana Environmental Quality Act and implementing regulations. Under the proposed Consent Decree, Defendant has agreed to pay a civil penalty of \$3.35 million, implement a State of Louisiana Beneficial Environmental Project valued at \$654,125 and implement a mitigation project to resolve the governments’ claims.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al. v. Firestone Polymers, LLC*, Case No. 2:21-cv-03464 and D.J. Ref. No. 90-5-2-1-11946. All comments must be submitted no later than thirty (30) days after the

publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: http://www.usdoj.gov/enrd/Consent_Decrees.html. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$18.75 (25 cents per page reproduction cost) without the Consent Decree attachments or \$29.50 with the attachments, payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021-21910 Filed 10-6-21; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Office of the Workers’ Compensation Programs

Agency Information Collection Activities; Comment Request; Rehabilitation Maintenance Certificate (OWCP-17)

AGENCY: Office of Workers’ Compensations, DOL

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, “Rehabilitation Maintenance Certificate (OWCP-17).” This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by December 6, 2021.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at suggs.anjanette@dol.gov.

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; by email: suggs.anjanette@dol.gov.

FOR FURTHER INFORMATION CONTACT:

Contact Anjanette Suggs by telephone at 202–354–9660 or by email at suggs.anjanette@dol.gov.

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Background: The Office of Workers' Compensation Programs (OWCP) administers the Federal Employees' Compensation Act (FECA) and the Longshore and Harbor Workers' Compensation Act (LHWCA). These acts provide vocational rehabilitation services to eligible workers with disabilities. 5 U.S.C. 8111(b) of the FECA provides that OWCP may pay an individual undergoing vocational rehabilitation a maintenance allowance, not to exceed \$200 a month. 33 U.S.C. 908(g) of the LHWCA provides that person(s) undergoing such vocational rehabilitation shall receive maintenance allowances as additional compensation. Form OWCP–17 is used to collect information necessary to determine the amount of any maintenance allowance to be paid. This information collection is currently approved for use through February 28, 2022. 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 under the PRA approves it and displays

a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(b) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Written comments will receive consideration, and be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Number 1240–0012. Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL—Office of Workers' Compensation Programs.

Type of Review: Extension.

Title of Collection: Rehabilitation Maintenance Certificate.

Form: OWCP–17.

OMB Number: 1240–0012.

Affected Public: Individuals or households.

Estimated Number of Respondents: 287.

Frequency: As needed.

Total Estimated Annual Responses: 694.

Estimated Average Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 118.

Total Estimated Annual Other Cost Burden: \$0.00.

Authority: 44 U.S.C. 3506(c)(2)(A).

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2021–21898 Filed 10–6–21; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Miner's Claim for Benefits Under the Black Lung Benefit's Act (CM–911) and Employment History (CM–911A) Division of Coal Mine Workers' Compensation

AGENCY: Office of Workers' Compensation Programs.

ACTION: Notice.

SUMMARY: Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Miner's Claim for Benefits under the Black Lung Benefit's Act (CM–911) and Employment History (CM–911A). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

DATES: Consideration will be given to all written comments received on or before December 6, 2021.

ADDRESSES: You may submit comments by mail, delivery service, or by hand to Ms. Anjanette Suggs, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210; by fax to (202) 354–9660; or by Email to Suggs.Anjanette@dol.gov. Please use only one method of transmission for comments (mail/delivery, fax, or Email). Please note that comments submitted after the comment period will not be considered.

FOR FURTHER INFORMATION: Contact Anjanette Suggs by telephone at 202–354–9660 or by email at suggs.anjanette@dol.gov.

SUPPLEMENTARY INFORMATION: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to

provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95).

I. *Background:* The Black Lung Benefits Act (BLBA), (30 U.S.C. 901 *et seq.*) provides benefits to coal miners who are totally disabled due to pneumoconiosis (black lung disease) and to certain survivors of miners. Miners entitled to benefits also receive medical benefits for treatment related to their pneumoconiosis and resulting disability. A miner who applies for black lung benefits must complete the CM-911 (application form). The completed form gives basic identifying information about the applicant and is the beginning of the development of the black lung claim. Title 20 CFR 725.304a authorizes this information collection. This form, when completed, provides a complete history of the miner's employment and helps to establish whether the individual currently or formerly worked in the nation's coal

mines and how long that employment lasted. Title 20 CFR 725.404(a) authorizes this information collection. This information collection is currently approved for use through March 31, 2022.

II. *Review Focus:* The Department of Labor is particularly interested in comments which:

- * Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- * evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- * enhance the quality, utility and clarity of the information to be collected; and

- * minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

III. *Current Actions:* The Department of Labor seeks the approval for the extension of this currently-approved information collection in order to carry out its responsibility to administer the Black Lung Benefits Act.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Agency: Office of Workers' Compensation Programs.

Type of Review: Revision.

Title: Miner's Claim for Benefits under the Black Lung Benefit's Act (CM-911) and Employment History (CM-911A).

OMB Number: 1240-0038.

Agency Number: CM-911 and CM-911A.

Affected Public: Individuals or households.

Form	Time to complete	Frequency of response	Number of respondents	Number of responses	Hours burden
CM-911	45	once	4,900	4,900	3,675
CM-911A	40	once	4,900	4,900	3,266
Totals			9,800	9,800	6,970

Total Respondents: 9,800.

Total Annual Responses: 9,800.

Average Time per Response: 42.5 minutes.

Estimated Total Burden Hours: 6,941.

Frequency: On occasion.

Total Burden Cost (capital/startup): \$0.

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2021-21912 Filed 10-6-21; 8:45 am]

BILLING CODE 4510-CK-P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 21-09]

Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance for Fiscal Year 2022

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: This report to Congress is provided in accordance with the

Millennium Challenge Act of 2003. The Millennium Challenge Act of 2003 requires the Millennium Challenge Corporation to publish a report that identifies the criteria and methodology that MCC intends to use to determine which candidate countries may be eligible to be considered for assistance under the Millennium Challenge Act for fiscal year 2022. The report is set forth in full below.

(Authority: Section 608(b)(2) of the Millennium Challenge Act of 2003, as amended, 22 U.S.C. 7707(b)(2) (the Act))

Dated: October 4, 2021.

Thomas G. Hohenthanner,

Acting VP/General Counsel and Corporate Secretary.

Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance for Fiscal Year 2022

This document explains how the Board of Directors (the Board) of the Millennium Challenge Corporation (MCC) will identify, evaluate, and select eligible countries for fiscal year (FY)

2022. Specifically, this document discusses the following:

- (I) Which countries MCC will evaluate
- (II) How the Board evaluates these countries
 - A. Overall evaluation
 - B. For selection of an eligible country for a first compact
 - C. For selection of an eligible country for a second or subsequent compact
 - D. For selection of an eligible country for a concurrent compact
 - E. For threshold program assistance
 - F. A note on potential transition to upper middle income country status after initial selection

This report is provided in accordance with section 608(b) of the Millennium Challenge Act of 2003, as amended (the Act), as more fully described in Appendix A.

(I) Which countries are evaluated?

MCC evaluates the policy performance of all candidate countries and statutorily-prohibited countries by dividing them into two income categories for the purposes of creating "scorecards." These categories are used to account for the income bias that occurs when countries with more per

capita resources perform better than countries with fewer. In FY 2022, those scorecard evaluation income categories¹ are:

- Countries whose gross national income (GNI) per capita is \$1,965 or less; and
- Countries whose GNI per capita is between \$1,966 and \$4,095.

Appendix B lists all candidate countries and statutorily-prohibited countries for scorecard evaluation purposes.

(II) How does the Board evaluate these countries?

A. Overall Evaluation

The Board looks at three legislatively-mandated factors when it evaluates any candidate country for compact eligibility: (1) Policy performance; (2) the opportunity to reduce poverty and generate economic growth; and (3) the availability of MCC funds.

(1) Policy Performance

Appendix C describes all 20 indicators, their definitions, what is required to “pass,” their source, and their relationship to the legislative criteria. Because of the importance of evaluating a country’s policy performance in a comparable, cross-country way, the Board relies to the maximum extent possible upon the best-available objective and quantifiable policy performance indicators. These indicators act as proxies for a country’s commitment to just and democratic governance, economic freedom, and investing in its people, per MCC’s founding legislation. Comprised of 20 third-party indicators in the categories of ruling justly, encouraging economic freedom, and investing in people, MCC scorecards are created for all candidate countries and statutorily-prohibited countries. To “pass” most indicators on its scorecard, a country’s score on each indicator must be above the median score *in its income group* (as defined above for scorecard evaluation purposes). For the inflation, political rights, civil liberties, and immunization rates² indicators, however, minimum or

¹ These income groups correspond to the definitions of low income countries and lower middle countries using the historical International Development Association (IDA) threshold published by the World Bank. MCC has used these categories to evaluate country performance since FY 2004. Our amended statute no longer uses those definitions for funding purposes, but we continue to use them for evaluation purposes.

² A minimum score required to pass has been established for the immunization rates indicator only when the median score is above a 90 percent immunization rate. Countries must score above 90 percent or the median for their scorecard income pool, whichever is lower, in order to pass the indicator.

maximum scores for “passing” have been established. In particular, the Board considers whether a country:

- Passed at least 10 of the 20 indicators, with at least one pass in each of the three categories,
- passed either the Political Rights or Civil Liberties indicator; and
- passed the Control of Corruption indicator.

While satisfaction of all three aspects means a country is termed to have “passed” the scorecard, the Board also considers whether the country performs “substantially worse” in any one policy category than it does on the scorecard overall.

The mandatory passing of either the Political Rights or Civil Liberties indicators is called the Democratic Rights “hard hurdle” on the scorecard, while the mandatory passing of the Control of Corruption indicator is called the Control of Corruption “hard hurdle.” Not passing either “hard hurdle” results in not passing the scorecard overall, regardless of whether at least 10 of the 20 other indicators are passed.

• *Democratic Rights “hard hurdle:”* This hurdle sets a minimum bar for democratic rights below which the Board will not consider a country for eligibility. Requiring that a country pass *either* the Political Rights *or* Civil Liberties indicator creates a democratic incentive for countries, recognizes the importance democracy plays in driving poverty-reducing economic growth, and holds MCC accountable to working with the best governed, poorest countries. When a candidate country is only passing one of the two indicators comprising the hurdle (instead of both), the Board will also closely examine why it is not passing the other indicator to understand what the score implies for the broader democratic environment and trajectory of the country. This examination will include consultation with both local and international civil society experts, among others.

• *Control of Corruption “hard hurdle:”* Corruption in any country is an unacceptable tax on economic growth and an obstacle to the private sector investment needed to reduce poverty. Accordingly, MCC seeks out partner countries that are committed to combatting corruption. It is for this reason that MCC also has the Control of Corruption “hard hurdle,” which helps ensure that MCC is working with countries where there is relatively strong performance in controlling corruption. Requiring the passage of the indicator provides an incentive for countries to demonstrate a clear commitment to controlling corruption,

and allows MCC to better understand the issue by seeing how the country performs relative to its peers and over time.

Together, the 20 policy performance indicators are the predominant basis for determining which eligible countries will be selected for MCC assistance, and the Board expects a country to be passing its scorecard at the point the Board decides to select the country for either a first or second/subsequent compact. The Board, however, also recognizes that even the best-available data has inherent challenges. Data gaps, real-time events versus data lags, the absence of narratives and nuanced detail, and other similar weaknesses affect each of these indicators. As such, the Board uses its judgment to interpret policy performance as measured by the scorecards. The Board may also consult other sources of information to enhance its understanding of the context underpinning a country’s policy performance beyond scorecard issues (e.g., specific policy issues related to trade, the treatment of civil society, other U.S. aid programs, financial sector performance, and security/foreign policy concerns). The Board uses its judgment on how best to weigh such information in assessing overall policy performance and making a final determination.

(2) The Opportunity To Reduce Poverty and Generate Economic Growth

While the Board considers a range of other information sources depending on the country, specific areas of attention typically include better understanding issues and trends in, and trajectory of:

- The state of democratic and human rights (especially vulnerable groups);³
- civil society’s perspective on salient governance issues;
- the control of corruption and rule of law;
- the potential for the private sector (both local and foreign) to lead investment and growth;
- poverty levels within a country; and
- the country’s institutional capacity.

Where applicable, the Board also considers MCC’s own experience and ability to reduce poverty and generate economic growth in a given country—such as considering MCC’s core areas of expertise and skills versus a country’s needs, and MCC’s capacity to work with a country.

This information provides greater clarity on the likelihood that MCC programs will have an appreciable impact on reducing poverty by

³ For example: Women; children; LGBT individuals; people with disabilities; and workers.

generating economic growth in a given country. The Board has used such information to better understand when a country's performance on a particular indicator may not be up to date or is about to change. It has also used supplemental information to decline to select countries that are otherwise passing their scorecards. More details on this subject (sometimes referred to as "supplemental information") can be found on MCC's website: www.mcc.gov/who-we-select/indicators.

(3) The Availability of MCC Funds

The final factor that the Board must consider when evaluating countries is the availability of funds. The agency's budget allocation is constrained, and often specifically limited, by provisions in our authorizing legislation and appropriations acts. MCC has a continuous pipeline of countries in compact development, compact implementation, threshold programs, and compact closure. Consequently, the Board factors in MCC's overall portfolio when making its selection decisions given the funding available for each planned or existing program.

The following subsections describe how each of these three legislatively-mandated factors are applied by the Board: Selection of countries for a compact, selection of countries for a second or subsequent compact, selection of countries for the threshold program, and selection of countries for a concurrent compact. A note follows on considerations for countries that might transition to upper middle income country status after initial selection.

B. Evaluation for Selection of Eligible Countries for a First Compact

When selecting eligible countries for a compact, the Board looks at all three legislatively-mandated aspects described in the previous section: (1) Policy performance, first and foremost as measured by the scorecards and bolstered through supplemental information (as described in the previous section); (2) the opportunity to reduce poverty and generate economic growth, examined through the use of other supporting information (as described in the previous section); and (3) available funding.

At a minimum, the Board considers whether a country passes its scorecard. It also examines supporting evidence that a country's commitment to just and democratic governance, economic freedom, and investing in its people is on a sound footing and performance is on a positive trajectory (especially on the "hard hurdles" of Democratic Rights and Control of Corruption), and that

MCC has the funds to support a meaningful compact with that country. Where applicable, previous threshold program information is also considered. The Board then weighs the information described above across each of the three dimensions.

During the compact development period following initial selection, the Board reevaluates a selected country based on this same approach.

C. Evaluation for Selection of Eligible Countries for a Subsequent Compact

Section 609(l) of the Act specifically authorizes MCC to enter into "one or more subsequent Compacts." MCC does not consider the eligibility of a country for a subsequent compact, however, before the country has completed its compact or is within 18 months of compact completion, (e.g., a second compact if it has completed or is within 18 months of completing its first compact). Selection for a subsequent compact is not automatic and is intended for countries that (1) exhibit successful performance on their previous compact; (2) exhibit improved scorecard policy performance during the partnership; and (3) exhibit a continued commitment to further their sector reform efforts in any subsequent partnership. As a result, the Board has an even higher standard when selecting countries for subsequent compacts.

(1) Successful Implementation of the Previous Compact

To evaluate the previous compact's success, the Board examines whether the compact succeeded within its budget and time limits, in particular by looking at three aspects:

- *The degree to which there is evidence of strong political will and management capacity:* Is the partnership characterized by the country ensuring that both policy reforms and the compact program itself are both being implemented to the best of that country's ability?

- *The degree to which the country has exhibited commitment and capacity to achieve program results:* Are the financial and project results being achieved; to what degree is the country committing its own resources to ensure the compact is a success; to what extent is the private sector engaged (if relevant); and other compact-specific issues?

- *The degree to which the country has implemented the compact in accordance with MCC's core policies and standards:* Is the country adhering to MCC's policies and procedures, including in critical areas such as: Remediating unresolved claims of fraud,

corruption, or abuse of funds; procurement; and monitoring and evaluation?

Details on the specific information types examined and sources used in each of the three areas are provided in Appendix D. Overall, the Board is looking for evidence that the previous compact will be or has been completed on time and on budget, and that there is a commitment to continued, robust reform going forward.

(2) Improved Scorecard Policy Performance

The Board also expects the country to have improved its overall scorecard policy performance during the partnership, and to pass the scorecard in the year of selection for the subsequent compact. The Board focuses on the following:

- The overall scorecard pass/fail rate over time, and what this suggests about underlying policy performance, as well as an examination of the underlying reasons;

- The progress over time on policy areas measured by both hard-hurdle indicators—Democratic Rights and Control of Corruption—including an examination of the underlying reasons; and

- Other indicator trajectories deemed relevant by the Board.

In all cases, while the Board expects the country to be passing its scorecard, other sources of information are examined to understand the nuance and reasons behind scorecard or indicator performance over time, including any real-time updates, methodological changes within the indicators themselves, shifts in the relevant candidate pool, or alternative policy performance perspectives (such as gleaned through consultations with civil society and related stakeholders). Other information sources are also consulted to look at policy performance over time in areas not covered by the scorecard, but that are deemed important by the Board (such as trade, foreign policy concerns, etc.).

(3) A Commitment to Further Sector Reform

The Board expects that subsequent compacts will endeavor to tackle deeper policy reforms necessary to unlock an identified constraint to growth. Consequently, the Board considers MCC's own experience during the previous compact in considering how committed the country is to reducing poverty and increasing economic growth, and tries to gauge the country's commitment to further sector reform

should it be selected for a subsequent compact. This includes:

- Assessing the country's delivery of policy reform during the previous compact (as described above);
- Assessing expectations of the country's ability and willingness to continue embarking on sector policy reform in a subsequent compact;
- Examining both other information sources describing the opportunity to reduce poverty by generating growth (as outlined in A.2 above), and the first compact's relative success overall, as already discussed; and
- Finally, considering how well funding can be leveraged for impact, given the country's experience in the previous compact.

Through this overall approach to selection for a subsequent compact, the Board applies the three legislatively mandated evaluation criteria (policy performance, the opportunity to reduce poverty and generate economic growth, and available funds) in a way that assesses the previous partnership from a compact success standpoint, a commitment to improved scorecard policy performance standpoint, and a commitment to continued sector policy reform standpoint. The Board then weighs all of the information described above in making a decision.

During the compact development period following initial selection, the Board reevaluates a selected country based on this same approach.

D. Evaluation for Concurrent Compacts

Section 609(k) of the Act authorizes MCC to enter into one additional concurrent compact with a country if one or both of the compacts with the country is for the purpose of regional economic integration, increased regional trade, or cross-border collaborations.

The fundamental criteria and process for the selection of countries for such compacts remains the same as those for the selection of countries for non-concurrent compacts: Countries continue to be evaluated and selected individually, as described in sections II.A, II.B, II.C, and II.F.

Section 609(k) also requires as a precondition for a concurrent compact that the Board determine that the country is making "considerable and demonstrable progress in implementing the terms of the existing Compact and supplementary agreements thereto." This statutory requirement is fully consistent with prior Board practice regarding the selection of a country for a non-concurrent compact. For a country where a concurrent compact is contemplated, the Board will take into account whether there is clear evidence

of success, as relevant to the phase of the current compact. Among other information, the Board will examine the evaluation criteria described in Section II.C.1 above, notably:

- The degree to which there is evidence of strong political will and management capacity;
- The degree to which the country has exhibited commitment and capacity to achieve program results; and
- The degree to which the country has implemented the compact in accordance with MCC's core policies and standards.

In addition to providing information to the Board so it can make its determination regarding the country's progress in implementing its current compact, MCC will provide the Board with additional information relating to the potential for regional economic integration, increased regional trade, or cross-border collaborations for any country being considered for a concurrent compact. This information may include items such as:

- The current state of a country's regional integration, such as common financial and political dialogue frameworks, integration of productive value chains, and cross-border flows of people, goods, and services.
- The current and potential level of trade between a country and its neighbors, including analysis of trade flows and unexploited potential for trade, and an assessment of the extent and significance of tariff and non-tariff barriers, including information regarding the patterns of trade.

- The potential gains from cross-border cooperation between a country and its neighbors to alleviate bilateral and regional bottlenecks to economic growth and poverty reduction, such as through physical infrastructure or coordinated policy and institutional reforms.

The Board can then weigh all information as a whole—the fundamental selection factors described in sections II.A, II.B, II.C, and II.F, the information regarding implementation of the current compact, and any additional relevant information regarding potential regional integration—to determine whether or not to direct MCC to seek to enter into a concurrent compact with a country.

E. Evaluation for Threshold Program Assistance

The Board may also evaluate countries for participation in the threshold program. Threshold programs provide assistance to candidate countries exhibiting a significant commitment to meeting the criteria

described in the previous subsections, but failing to meet such requirements. Specifically, in examining a candidate country's policy performance, the opportunity to reduce poverty and generate economic growth, and available funds, the Board will consider whether a country appears to be on a trajectory to becoming viable for compact eligibility in the medium or short term.

F. A Note on Potential Transition to Upper Middle Income Country (UMIC) Status After Initial Selection

Some candidate countries may have a high per capita income or a high growth rate that implies there is a chance they could transition to UMIC status during the life of an MCC partnership. In such cases, it is not possible to accurately predict if or when such country may transition to UMIC status.

Nonetheless, such countries may have more resources at their disposal for funding their own growth and poverty reduction strategies. As a result, in addition to using the regular selection criteria described in the previous sections, the Board will use its discretion to assess both the need and the opportunity presented by partnering with such a country, in order to ensure that there is a higher bar for possible selection.

Specifically, if a candidate country with a high probability of transitioning to UMIC status is under consideration for selection, the Board will examine additional data and information related to the following:

- Whether the country faces significant challenges accessing other sources of development financing (such as international capital, domestic resources, and other donor assistance) and, if so, whether MCC grant financing would be an appropriate tool;
- Whether the nature of poverty in the country (for example, high inequality or poverty headcount ratios relative to peer countries) presents a clear and strategic opportunity for MCC to assist the country in reducing such poverty through projects that spur economic growth;
- Whether the country demonstrates particularly strong policy performance, including policies and actions that demonstrate a clear priority on poverty reduction; and
- Whether MCC can reasonably expect that the country would contribute a significant amount of funding to the compact.

These additional criteria would then be applied in any additional years of selection as the country continues to develop its compact. Should a country

eventually transition to UMIC status during compact development, a country would no longer be a candidate for selection for that fiscal year. Continuing compact development beyond that point would then be at the Board's discretion.

Appendix A: Statutory Basis for This Report

This report to Congress is provided in accordance with section 608(b) of the Millennium Challenge Act of 2003, as amended (the Act), 22 U.S.C. 7707(b).

Section 605 of the Act authorizes the provision of assistance to countries that enter into a Millennium Challenge Compact with the United States to support policies and programs that advance the progress of such countries in achieving lasting economic growth and poverty reduction. The Act requires MCC to take a number of steps in selecting countries for compact assistance for FY 2022 based on the countries' demonstrated commitment to just and democratic governance, economic freedom, and investing in their people, MCC's opportunity to reduce poverty and generate economic growth in the country, and the availability of funds. These steps include the submission of reports to the congressional committees specified in the Act and publication of information in the **Federal Register** that identify:

(1) The countries that are "candidate countries" for assistance for FY 2022 based on per capita income levels and eligibility to receive assistance under U.S. law (section 608(a) of the Act; 22 U.S.C. 7707(a));

(2) The criteria and methodology that MCC's Board of Directors (Board) will use to measure and evaluate policy performance of the candidate countries consistent with the requirements of section 607 of the Act (22 U.S.C. 7706) in order to determine "eligible countries" from among the "candidate countries" (section 608(b) of the Act; 22 U.S.C. 7707(b)); and

(3) The list of countries determined by the Board to be "eligible countries" for FY 2022, with justification for eligibility determination and selection for compact negotiation, including those eligible countries with which MCC will seek to enter into compacts (section 608(d) of the Act; 22 U.S.C. 7707(d)).

This report satisfies item 2 above.

Appendix B: Lists of All Candidate Countries and Statutorily-Prohibited Countries for Evaluation Purposes

Income Groups for Scorecards

Since MCC was created, it has relied on the *World Bank's gross national income (GNI) per capita income data*

(Atlas method) and the historical ceiling for eligibility as set by the World Bank's International Development Association (IDA) to divide countries into two income categories for purposes of creating scorecards. These categories are used to account for the income bias that occurs when countries with more per capita resources perform better than countries with fewer. Using the historical IDA eligibility ceiling for the scorecard evaluation groups ensures that the poorest countries compete with their income level peers and are not compared against countries with more resources to mobilize.

MCC will continue to use the historical IDA classifications for eligibility to categorize countries in two groups for purposes of FY 2022 scorecard comparisons:

- Countries with GNI per capita equal to or less than IDA's historical ceiling for eligibility (*i.e.*, \$1,965 for FY 2022); and

- Countries with GNI per capita above IDA's historical ceiling for eligibility but below the World Bank's upper middle income country threshold (*i.e.*, \$1,966 and \$4,095 for FY 2022).

The list of countries for FY 2022 scorecard assessments is set forth below:

Countries With GNI Per Capita of \$1,965 or Less

1. Afghanistan
2. Benin
3. Burkina Faso
4. Burma
5. Burundi
6. Cambodia
7. Cameroon
8. Central African Republic
9. Chad
10. Comoros
11. Congo, Democratic Republic of the
12. Congo, Republic of the
13. Eritrea
14. Ethiopia
15. Gambia, The
16. Guinea
17. Guinea-Bissau
18. Haiti
19. India
20. Kenya
21. Korea, North
22. Kyrgyzstan
23. Lesotho
24. Liberia
25. Madagascar
26. Malawi
27. Mali
28. Mauritania
29. Mozambique
30. Nepal
31. Nicaragua
32. Niger
33. Pakistan
34. Rwanda

35. Senegal
36. Sierra Leone
37. Somalia
38. South Sudan
39. Sudan
40. Syria
41. Tajikistan
42. Tanzania
43. Timor-Leste
44. Togo
45. Uganda
46. Uzbekistan
47. Yemen
48. Zambia
49. Zimbabwe

Countries With GNI Per Capita Between \$1,966 and \$4,095

1. Algeria
2. Angola
3. Bangladesh
4. Belize
5. Bhutan
6. Bolivia
7. Cabo Verde
8. Côte d'Ivoire
9. Djibouti
10. Egypt
11. El Salvador
12. Eswatini
13. Ghana
14. Honduras
15. Indonesia
16. Iran
17. Kiribati
18. Laos
19. Micronesia, Federated States of
20. Mongolia
21. Morocco
22. Nigeria
23. Papua New Guinea
24. Philippines
25. Samoa
26. Sao Tome and Principe
27. Solomon Islands
28. Sri Lanka
29. Tunisia
30. Ukraine
31. Vanuatu
32. Vietnam

Statutorily-Prohibited Countries

1. Burma
2. Cambodia
3. Comoros
4. Eritrea
5. Ethiopia
6. Guinea-Bissau
7. Iran
8. Korea, North
9. Mali
10. Nicaragua
11. South Sudan
12. Sri Lanka
13. Sudan
14. Syria
15. Zimbabwe

Appendix C: Indicator Definitions

The following indicators will be used to measure candidate countries'

demonstrated commitment to the criteria found in section 607(b) of the Act. The indicators are intended to assess the degree to which the political and economic conditions in a country serve to promote broad-based sustainable economic growth and reduction of poverty and thus provide a sound environment for the use of MCC funds. The indicators are not goals in themselves; rather, they are proxy measures of policies that are linked to broad-based sustainable economic growth. The indicators were selected based on (i) their relationship to economic growth and poverty reduction; (ii) the number of countries they cover; (iii) transparency and availability; and (iv) relative soundness and objectivity. Where possible, the indicators are developed by independent sources. Listed below is a brief summary of the indicators (a detailed rationale for the adoption of these indicators can be found in the public Guide to the Indicators on MCC's website at www.mcc.gov/who-we-select/indicators).

Ruling Justly

1. *Political Rights*: Independent experts rate countries on the prevalence of free and fair electoral processes; political pluralism and participation of all stakeholders; government accountability and transparency; freedom from domination by the military, foreign powers, totalitarian parties, religious hierarchies and economic oligarchies; and the political rights of minority groups, among other things. Pass: Score must be above the minimum score of 17 out of 40. Source: *Freedom House*

2. *Civil Liberties*: Independent experts rate countries on freedom of expression and belief; association and organizational rights; rule of law and human rights; and personal autonomy and economic rights, among other things. Pass: Score must be above the minimum score of 25 out of 60. Source: *Freedom House*

3. *Freedom of Information*: Measures the legal and practical steps taken by a government to enable or allow information to move freely through society; this includes measures of press freedom, national freedom of information laws, and the extent to which a county is shutting down social media or the internet. Pass: Score must be above the median score for the income group. Source: *Reporters Without Borders/Access Now/Centre for Law and Democracy*.

4. *Government Effectiveness*: An index of surveys and expert assessments that rate countries on the quality of

public service provision; civil servants' competency and independence from political pressures; and the government's ability to plan and implement sound policies, among other things. Pass: Score must be above the median score for the income group. Source: *Worldwide Governance Indicators (World Bank/Brookings)*

5. *Rule of Law*: An index of surveys and expert assessments that rate countries on the extent to which the public has confidence in and abides by the rules of society; the incidence and impact of violent and nonviolent crime; the effectiveness, independence, and predictability of the judiciary; the protection of property rights; and the enforceability of contracts, among other things. Pass: Score must be above the median score for the income group. Source: *Worldwide Governance Indicators (World Bank/Brookings)*

6. *Control of Corruption*: An index of surveys and expert assessments that rate countries on: "grand corruption" in the political arena; the frequency of petty corruption; the effects of corruption on the business environment; and the tendency of elites to engage in "state capture," among other things. Pass: Score must be above the median score for the income group. Source: *Worldwide Governance Indicators (World Bank/Brookings)*

Encouraging Economic Freedom

1. *Fiscal Policy*: General government net lending/borrowing as a percent of gross domestic product (GDP), averaged over a three year period. Net lending/borrowing is calculated as revenue minus total expenditure. The data for this measure comes from the IMF's World Economic Outlook. Pass: Score must be above the median score for the income group. Source: *The International Monetary Fund's World Economic Outlook Database*

2. *Inflation*: The most recent average annual change in consumer prices. Pass: Score must be 15 percent or less. Source: *The International Monetary Fund's World Economic Outlook Database*

3. *Regulatory Quality*: An index of surveys and expert assessments that rate countries on the burden of regulations on business; price controls; the government's role in the economy; and foreign investment regulation, among other areas. Pass: Score must be above the median score for the income group. Source: *Worldwide Governance Indicators (World Bank/Brookings)*

4. *Trade Policy*: A measure of a country's openness to international trade based on weighted average tariff rates and non-tariff barriers to trade.

Pass: Score must be above the median score for the income group. Source: *The Heritage Foundation*

5. *Gender in the Economy*: An index that measures the extent to which laws provide men and women equal capacity to generate income or participate in the economy, including factors such as the capacity to access institutions, get a job, register a business, sign a contract, open a bank account, choose where to live, to travel freely, property rights protections, protections against domestic violence, and child marriage, among others. Pass: Score must be above the median score for the income group. Source: *Women, Business, and the Law (World Bank) and the WORLD Policy Analysis Center (UCLA)*

6. *Land Rights and Access*: An index that rates countries on the extent to which the institutional, legal, and market framework provides secure land tenure and equitable access to land in rural areas and the extent to which men and women have the right to private property in practice and in law. Pass: Score must be above the median score for the income group. Source: *The International Fund for Agricultural Development and Varieties of Democracy Index*

7. *Access to Credit*: An index that ranks countries based on access and use of formal and informal financial services as measured by the number of bank branches and ATMs per 100,000 adults and the share of adults that have an account at a formal or informal financial institution. Pass: Score must be above the median score for the income group. Source: *Financial Development Index (International Monetary Fund) and Findex (World Bank)*

8. *Business Start-Up*: An index that rates countries based on surveys of firms on the time to obtain an operating license and whether permits and licenses are the biggest obstacle to business. Pass: Score must be above the median score for the income group. Source: *World Bank Enterprise Surveys*

Investing in People

1. *Public Expenditure on Health*: Total current expenditures on health by government (excluding funding sourced from external donors) at all levels divided by GDP. Pass: Score must be above the median score for the income group. Source: *The World Health Organization*

2. *Total Public Expenditure on Primary Education*: Total expenditures on primary education by government at all levels divided by GDP. Pass: Score must be above the median score for the income group. Source: *The United Nations Educational, Scientific and*

Cultural Organization and National Governments

3. *Natural Resource Protection*: Assesses whether countries are protecting up to 17 percent of all their biomes (e.g., deserts, tropical rainforests, grasslands, savannas and tundra). Pass: Score must be above the median score for the income group. Source: *The Center for International Earth Science Information Network and the Yale Center for Environmental Law and Policy*

4. *Immunization Rates*: The average of DPT3 and measles immunization coverage rates for the most recent year available. Pass: Score must be above either the median score for the income group or 90 percent, whichever is lower. Source: *The World Health Organization and the United Nations Children's Fund*

5. *Girls Education*:
 a. *Girls' Primary Completion Rate*: The number of female students enrolled in the last grade of primary education minus repeaters divided by the population in the relevant age cohort (gross intake ratio in the last grade of primary). Countries with a GNI/capita of \$1,965 or less are assessed on this indicator. Pass: Score must be above the median score for the income group. Source: *United Nations Educational, Scientific and Cultural Organization*

b. *Girls Secondary Enrollment Education*: The number of female pupils enrolled in lower secondary school, regardless of age, expressed as a percentage of the population of females in the theoretical age group for lower secondary education. Countries with a GNI/capita between \$1,966 and \$4,095 are assessed on this indicator instead of Girls Primary Completion Rates. Pass: Score must be above the median score for the income group. Source: *United Nations Educational, Scientific and Cultural Organization*

6. *Child Health*: An index made up of three indicators: (i) Access to improved water, (ii) access to improved sanitation, and (iii) child (ages 1–4) mortality. Pass: Score must be above the median score for the income group. Source: *The Center for International Earth Science Information Network and the Yale Center for Environmental Law and Policy*

Relationship to Legislative Criteria

Within each policy category, the Act sets out a number of specific selection

criteria. A set of objective and quantifiable policy indicators is used to inform eligibility decisions for assistance and to measure the relative performance by candidate countries against these criteria. The Board's approach to determining eligibility ensures that performance against each of these criteria is assessed by at least one of the objective indicators. Most are addressed by multiple indicators. The specific indicators appear in parentheses next to the corresponding criterion set out in the Act.

Section 607(b)(1): Just and democratic governance, including a demonstrated commitment to—

(A) promote political pluralism, equality and the rule of law (*Political Rights, Civil Liberties, Rule of Law, and Gender in the Economy*);

(B) respect human and civil rights, including the rights of people with disabilities (*Political Rights, Civil Liberties, and Freedom of Information*);

(C) protect private property rights (*Civil Liberties, Regulatory Quality, Rule of Law, and Land Rights and Access*);

(D) encourage transparency and accountability of government (*Political Rights, Civil Liberties, Freedom of Information, Control of Corruption, Rule of Law, and Government Effectiveness*);

(E) combat corruption (*Political Rights, Civil Liberties, Rule of Law, Freedom of Information, and Control of Corruption*); and

(F) the quality of the civil society enabling environment (*Civil Liberties, Freedom of Information, and Rule of Law*)

Section 607(b)(2): Economic freedom, including a demonstrated commitment to economic policies that—

(A) encourage citizens and firms to participate in global trade and international capital markets (*Fiscal Policy, Inflation, Trade Policy, and Regulatory Quality*);

(B) promote private sector growth (*Inflation, Business Start-Up, Fiscal Policy, Land Rights and Access, Access to Credit, Gender in the Economy, and Regulatory Quality*);

(C) strengthen market forces in the economy (*Fiscal Policy, Inflation, Trade Policy, Business Start-Up, Land Rights and Access, Access to Credit, and Regulatory Quality*); and

(D) respect worker rights, including the right to form labor unions (*Civil Liberties and Gender in the Economy*)

Section 607(b)(3): Investments in the people of such country, particularly women and children, including programs that—

(A) promote broad-based primary education (*Girls' Primary Completion Rate, Girls' Secondary Education Enrollment Rate, and Total Public Expenditure on Primary Education*);

(B) strengthen and build capacity to provide quality public health and reduce child mortality (*Immunization Rates, Public Expenditure on Health, and Child Health*); and

(C) promote the protection of biodiversity and the transparent and sustainable management and use of natural resources (*Natural Resource Protection*).

Appendix D: Subsequent and Concurrent Compact Considerations

MCC reporting and data in the following chart are used to assess compact performance of MCC compact countries nearing the end of compact implementation (i.e., within 18 months of compact end date), or for current MCC compact countries under consideration for a concurrent compact, where appropriate. Some reporting used for assessment may contain sensitive information and adversely affect implementation or MCC-partner country relations. This information is for MCC's internal use and is not made public. However, key implementation information is summarized in compact status and results reports that are published quarterly on MCC's website under MCC country programs (www.mcc.gov/where-we-work) or monitoring and evaluation (www.mcc.gov/our-impact/m-and-e) web pages.

For completed compacts, additional information is used to assess compact performance and is found in a country's Star Report. The Star Report and its associated quarterly business process capture key information to provide a framework for results and improve the ability to disseminate learning and evidence throughout the lifecycle of an MCC investment from selection to final evaluation. For each compact and threshold program, evidence is collected on performance indicators, evaluation results, partnerships, sustainability efforts, and learning, among other elements.

Topic	MCC reporting/ data source	Published documents
COUNTRY PARTNERSHIP		
Political Will: <ul style="list-style-type: none"> • Status of major conditions precedent. • Program oversight/implementation. <ul style="list-style-type: none"> ○ project restructures. ○ partner response to accountable entity capacity issues. • Political independence of the accountable entity. Management Capacity: <ul style="list-style-type: none"> • Project management capacity. • Project performance. • Level of MCC intervention/oversight. • Relative level of resources required. 	<ul style="list-style-type: none"> • <i>Quarterly implementation reporting.</i> • <i>Quarterly results reporting.</i> • <i>MCC Star Reports.</i> 	<ul style="list-style-type: none"> • <i>Quarterly results published as “Table of Key Performance Indicators” (available by country): https://www.mcc.gov/our-impact/m-and-e.</i> • <i>Star Reports (available by country): https://www.mcc.gov/resources?fwp_resource_type=star-report.</i>
PROGRAM RESULTS		
Financial Results: <ul style="list-style-type: none"> • Commitments—including contributions to compact funding. • Disbursements. Project Results: <ul style="list-style-type: none"> • Output, outcome, objective targets. • Accountable entity commitment to ‘focus on results’. • Accountable entity cooperation on impact evaluation. • Percent complete for process/outputs. • Relevant outcome data. • Details behind target delays. Target Achievements:	<ul style="list-style-type: none"> • <i>Indicator tracking tables.</i> • <i>Quarterly financial reporting.</i> • <i>Quarterly implementation reporting.</i> • <i>Quarterly results reporting.</i> • <i>Impact evaluations.</i> • <i>MCC Star Reports.</i> 	<ul style="list-style-type: none"> • <i>Monitoring and Evaluation Plans (available by country): https://www.mcc.gov/our-impact/m-and-e.</i> • <i>Quarterly results published as “Table of Key Performance Indicators” (available by country): https://www.mcc.gov/our-impact/m-and-e.</i> • <i>Star Reports (available by country): https://www.mcc.gov/resources?fwp_resource_type=star-report.</i>
ADHERENCE TO STANDARDS		
<ul style="list-style-type: none"> • Procurement <ul style="list-style-type: none"> • Environmental and social. • Fraud and corruption. • Program closure. • Monitoring and evaluation. • All other legal provisions. 	<ul style="list-style-type: none"> • <i>Audits (GAO and OIG).</i> • <i>Quarterly implementation reporting.</i> • <i>MCC Star Reports.</i> 	<ul style="list-style-type: none"> • <i>Published OIG and GAO audits.</i> • <i>Star Reports (available by country): https://www.mcc.gov/resources?fwp_resource_type=star-report.</i>
COUNTRY SPECIFIC		
Sustainability: <ul style="list-style-type: none"> • Implementation entity. • MCC investments. Role of private sector or other donors: <ul style="list-style-type: none"> • Other relevant investors/investments. • Other donors/programming. • Status of related reforms. • Trajectory of private sector involvement going forward. 	<ul style="list-style-type: none"> • <i>Quarterly implementation reporting.</i> • <i>Quarterly results reporting.</i> • <i>MCC Star Reports.</i> 	<ul style="list-style-type: none"> • <i>Quarterly results published as “Table of Key Performance Indicators” (available by country): https://www.mcc.gov/our-impact/m-and-e.</i> • <i>Star Reports (available by country): https://www.mcc.gov/resources?fwp_resource_type=star-report.</i>

[FR Doc. 2021–21916 Filed 10–6–21; 8:45 am]

BILLING CODE 9211–03–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0187]

Environmental Assessment and Finding of No Significant Impact of Independent Spent Fuel Storage Facilities Decommissioning Funding Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is publishing this

notice regarding the issuance of a final environmental assessment (EA) and a finding of no significant impact (FONSI) for its review and approval of the initial and updated decommissioning funding plans (DFPs) submitted by independent spent fuel storage installation (ISFSI) licensees for the ISFSIs listed in the “Discussion” section of this document. **DATES:** The EA and FONSI referenced in this document are available on October 7, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0187 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2021–0187. 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.

- *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.

FOR FURTHER INFORMATION CONTACT: Tilda Liu, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 404-997-4730, email: Tilda.Liu@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering the approval of the initial and updated DFPs submitted by ISFSI licensees. The NRC staff has prepared a Final EA and FONSI determination for each of the initial and

updated ISFSI DFPs in accordance with the NRC regulations in part 51 of title 10 of the *Code of Federal Regulations* (10 CFR), “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” which implement the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

The NRC requires its licensees to plan for the eventual decommissioning of their licensed facilities prior to license termination. On June 17, 2011, the NRC published a final rule in the **Federal Register** amending its decommissioning planning regulations (76 FR 35511). The final rule amended the NRC regulation, 10 CFR 72.30, which concerns financial assurance and decommissioning for ISFSIs. This regulation requires each holder of, or applicant for, a license under 10 CFR part 72 to submit a DFP for the NRC’s review and approval. The DFP is to demonstrate the licensee’s financial assurance, *i.e.*, that funds will be available to decommission the ISFSI.

The NRC staff will later publish its financial analyses of the DFP submittals which will be available for public inspection in ADAMS.

II. Discussion

The table in this notice includes the plant name, docket number, licensee, and ADAMS accession number for the Final EA and FONSI determination for each of the individual ISFSIs. The table also includes the ADAMS accession numbers for other relevant documents, including the initial and updated DFP submittals. For further details with respect to these actions, see the NRC staff’s Final EA and FONSI determinations which are available for public inspection in ADAMS and at <https://www.regulations.gov> under Docket ID NRC-2021-0187. For additional direction on accessing information related to this document, see the **ADDRESSES** section of this document.

FINDING OF NO SIGNIFICANT IMPACT

Browns Ferry Nuclear Plant

Docket No	72-52.
Licensee	Tennessee Valley Authority (TVA).
Proposed Action	The NRC’s review and approval of TVA’s initial and updated DFPs submitted in accordance with 10 CFR 72.30(b) and (c).
Environmental Impact of Proposed Action	The NRC staff has determined that the proposed action, the review and approval of TVA’s initial and updated DFPs, submitted in accordance with 10 CFR 72.30(b) and (c), will not authorize changes to licensed operations or maintenance activities, or result in changes in the types, characteristics, or quantities of radiological or non-radiological effluents released into the environment from the ISFSI, or result in the creation of solid waste. Moreover, the approval of the initial and updated DFPs will not authorize any construction activity, facility modification, or other land-disturbing activity. The NRC staff has concluded that the proposed action is a procedural and administrative action that will not have a significant impact on the environment.
Finding of No Significant Impact	The proposed action does not require changes to the ISFSI’s licensed routine operations, maintenance activities, or monitoring programs, nor does it require new construction or land-disturbing activities. The scope of the proposed action concerns only the NRC’s review and approval of TVA’s initial and updated DFPs. The scope of the proposed action does not include, and will not result in, the review and approval of decontamination or decommissioning activities or license termination for the ISFSI or for other parts of Browns Ferry Nuclear Plant (BFN). Therefore, the NRC staff determined that approval of the initial and updated DFPs for the BFN ISFSI will not significantly affect the quality of the human environment, and accordingly, the staff has concluded that a FONSI is appropriate. The NRC staff further finds that preparation of an environmental impact statement is not required.
Available Documents	U.S. Nuclear Regulatory Commission. Review of the Draft EA and FONSI for the Browns Ferry Nuclear Plant Units 1, 2 and 3 ISFSI DFP, dated July 8, 2016. ADAMS Package Accession No. ML16190A282. U.S. Nuclear Regulatory Commission. ESA Section 7 No Effect Determination for ISFSI DFP Reviews (Note to File), dated May 15, 2017. ADAMS Accession No. ML17135A062. U.S. Nuclear Regulatory Commission. Request for Additional Information Regarding TVA’s DFP Update for Browns Ferry and Sequoyah ISFSIs, dated May 17, 2018. ADAMS Package Accession No. ML18138A109.

FINDING OF NO SIGNIFICANT IMPACT—Continued

	<p>U.S. Nuclear Regulatory Commission. Final EA and FONSI for TVA's Initial and Updated DFPs Submitted in Accordance with 10 CFR 72.30(b) and (c) for Browns Ferry Nuclear Plant, dated September 29, 2021. ADAMS Accession No. ML21246A293.</p> <p>Tennessee Valley Authority. DFPs for ISFSIs, dated December 17, 2012. ADAMS Accession No. ML12356A039.</p> <p>Tennessee Valley Authority. Triennial DFPs for ISFSIs, dated December 17, 2015. ADAMS Accession No. ML15352A046.</p> <p>Tennessee Valley Authority. Response to Request for Additional Information Regarding DFP Update for Browns Ferry Nuclear Plant and Sequoyah Nuclear Plant ISFSIs, Docket Nos. 72-052 and 72-034, dated July 23, 2018. ADAMS Accession No. ML18205A476.</p>
Sequoyah Nuclear Plant	
Docket No	72-34.
Licensee	Tennessee Valley Authority (TVA).
Proposed Action	The NRC's review and approval of TVA's initial and updated DFPs submitted in accordance with 10 CFR 72.30(b) and (c).
Environmental Impact of Proposed Action	The NRC staff has determined that the proposed action, the review and approval of TVA's initial and updated DFPs, submitted in accordance with 10 CFR 72.30(b) and (c), will not authorize or changes to licensed operations or maintenance activities, or result in changes in the types, characteristics, or quantities of radiological or non-radiological effluents released into the environment from the ISFSI, or result in the creation of solid waste. Moreover, the approval of the initial and updated DFPs will not authorize any construction activity, facility modification, or other land-disturbing activity. The NRC staff has concluded that the proposed action is a procedural and administrative action that will not have a significant impact on the environment.
Finding of No Significant Impact	The proposed action does not require changes to the ISFSI's licensed routine operations, maintenance activities, or monitoring programs, nor does it require new construction or land-disturbing activities. The scope of the proposed action concerns only the NRC's review and approval of TVA's DFPs. The scope of the proposed action does not include, and will not result in, the review and approval of decontamination or decommissioning activities or license termination for the ISFSI or for other parts of the Sequoyah Nuclear Plant (SQN). Therefore, the NRC staff determined that approval of the initial and updated DFPs for the SQN ISFSI will not significantly affect the quality of the human environment, and accordingly, the staff has concluded that a FONSI is appropriate. The NRC staff further finds that preparation of an environmental impact statement is not required.
Available Documents	<p>U.S. Nuclear Regulatory Commission. Review of the Draft EA and FONSI for the Sequoyah Nuclear Plant Units 1 and 2 ISFSI DFP, dated August 17, 2017. ADAMS Accession No. ML17226A201.</p> <p>U.S. Nuclear Regulatory Commission. ESA Section 7 No Effect Determination for ISFSI DFP Reviews (Note to File), dated May 15, 2017. ADAMS Accession No. ML17135A062.</p> <p>U.S. Nuclear Regulatory Commission. Request for Additional Information Regarding TVA's DFP Update for Browns Ferry and Sequoyah ISFSIs, dated May 17, 2018. ADAMS Package Accession No. ML18138A109.</p> <p>U.S. Nuclear Regulatory Commission. Final EA and FONSI for TVA's Initial and Updated DFPs Submitted in Accordance with 10 CFR 72.30(b) and (c) for Browns Ferry Nuclear Plant, dated September 29, 2021. ADAMS Accession No. ML21246A279.</p> <p>Tennessee Valley Authority. DFPs for ISFSIs, dated December 17, 2012. ADAMS Accession No. ML12356A039.</p> <p>Tennessee Valley Authority. Triennial DFPs for ISFSIs, dated December 17, 2015. ADAMS Accession No. ML15352A046.</p> <p>Tennessee Valley Authority. Response to Request for Additional Information Regarding DFP Update for Browns Ferry Nuclear Plant and Sequoyah Nuclear Plant ISFSIs, Docket Nos. 72-052 and 72-034, dated July 23, 2018. ADAMS Accession No. ML18205A476.</p>

Dated: October 4, 2021.

For the Nuclear Regulatory Commission.

John B. McKirgan,

Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021-21957 Filed 10-6-21; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93229; File No. SR-CboeBZX-2020-053]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Setting Aside Action by Delegated Authority and Approving a Proposed Rule Change, as Modified by Amendment Nos. 2 and 4, To List and Trade Shares of the 2x Long VIX Futures ETF Under BZX Rule 14.11(f)(4) (Trust Issued Receipts)

October 1, 2021.

I. Introduction

On June 23, 2020, Cboe BZX Exchange, Inc. (“BZX”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act” or “Exchange Act”) ¹ and Rule 19b-4 thereunder,² a proposed rule change to list and trade shares (“Shares”) of the 2x Long VIX Futures ETF (“Fund”), a series of VS Trust (“Trust”), under BZX Rule 14.11(f)(4).³

On March 5, 2021, the Commission, acting through authority delegated to the Division of Trading and Markets

(“Division”),⁴ noticed the filing of Amendment Nos. 2 and 4 and approved the proposed rule change, as modified by Amendment Nos. 2 and 4, on an accelerated basis.⁵ On March 5, 2021, the Assistant Secretary of the Commission notified BZX that, pursuant to Commission Rule of Practice 431,⁶ the Commission would review the Division’s action pursuant to delegated authority and that the Division’s action pursuant to delegated authority was stayed until the Commission ordered otherwise.⁷ On April 7, 2021, the Commission issued a scheduling order, pursuant to Commission Rule of Practice 431, providing until May 7, 2021 for any party or other person to file a written statement in support of, or in opposition to, the Approval Order.⁸

The Commission has conducted a *de novo* review of BZX’s proposal, giving careful consideration to the entire record, including all comments and statements submitted, to determine whether the proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. Under Section 19(b)(2)(C) of the Act, the Commission must approve the proposed rule change of a self-regulatory organization (“SRO”) if the Commission finds that the proposed rule change is consistent with the requirements of the Act and the applicable rules and regulations thereunder; if it does not make such a finding, the Commission must disapprove the proposed rule change.⁹ Additionally, under Rule 700(b)(3) of the Commission’s Rules of Practice, the “burden to demonstrate that a proposed rule change is consistent with the Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change.”¹⁰ The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently

detailed and specific to support an affirmative Commission finding.¹¹ Any failure of a self-regulatory organization to provide the information required by Rule 19b-4 and elicited on Form 19b-4 may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the rules and regulations thereunder that are applicable to the self-regulatory organization.¹²

For the reasons discussed further herein, BZX has met its burden to show that the proposed rule change is consistent with the Act, and this order sets aside the Approval Order and approves BZX’s proposed rule change, as modified by Amendment Nos. 2 and 4. In particular, the Commission concludes that the record before the Commission demonstrates that BZX’s proposal is consistent with Section 6(b)(5) of the Act,¹³ which requires that the rules of a national securities exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

II. Summary of the Proposal

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(f)(4), which governs the listing and trading of Trust Issued Receipts¹⁴ on the Exchange. Volatility Shares LLC (“Sponsor”) serves as the Sponsor of the Trust. The Fund’s investment objective is to provide a return that is 200% of the return of its benchmark index for a single day. The benchmark for the Fund is the Long VIX Futures Index (LONGVOL) (“Index”),¹⁵ which

¹¹ See *id.*

¹² See *id.* See also 17 CFR 240.19b-4.

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ Rule 14.11(f)(4) applies to Trust Issued Receipts that invest in “Financial Instruments,” defined in Rule 14.11(f)(4)(A)(iv) as any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars and floors; and swap agreements.

¹⁵ The Index is sponsored by Cboe Global Indexes (“Index sponsor”). The Index sponsor is not a registered broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to the broker-dealer affiliate regarding access to information concerning the composition of and/or changes to the Index. In addition, the Index sponsor has implemented and will maintain procedures that are designed to prevent the use and dissemination of material, non-public information regarding the Index.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ On June 26, 2020, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on July 10, 2020. See Securities Exchange Act Release No. 89234 (Jul. 6, 2020), 85 FR 41644. On August 13, 2020, the Commission extended the time period for Commission action on the proposed rule change. See Securities Exchange Act Release No. 89545, 85 FR 51124 (Aug. 19, 2020). On October 7, 2020, the Commission instituted proceedings pursuant to Section 19(b)(2)(B) of the Act (15 U.S.C. 78s(b)(2)(B)) to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1. See Securities Exchange Act Release No. 90118, 85 FR 64563 (Oct. 13, 2020) (“OIP”). On December 15, 2020, the Commission designated a longer period for Commission action on the proposed rule change. See Securities Exchange Act Release No. 90671, 85 FR 83136 (Dec. 21, 2020). On February 1, 2021, the Exchange filed Amendment No. 2 to the proposed rule change, which replaced and superseded the proposed rule change as modified by Amendment No. 1. On February 16, 2021, the Exchange submitted Amendment No. 3 to the proposed rule change and, on February 19, 2021, the Exchange withdrew Amendment No. 3. On February 19, 2021, the Exchange filed partial Amendment No. 4 to the proposed rule change.

⁴ 17 CFR 200.30-3(a)(12).

⁵ See Securities Exchange Act Release No. 91265 (Mar. 5, 2021), 86 FR 13922 (Mar. 11, 2021) (“Approval Order”).

⁶ 17 CFR 201.431.

⁷ See letter from J. Matthew DeLesDernier, Assistant Secretary, Commission, to Kyle Murray, Vice President and Associate General Counsel, Cboe Global Markets, dated March 5, 2021, available at: <https://www.sec.gov/rules/sro/cboebzx/2018/34-91265-letter-from-assistant-secretary.pdf>.

⁸ See Securities Exchange Act Release No. 91501, 86 FR 19292 (Apr. 13, 2021). Comments on the proposed rule change, including statements concerning the Approval Order are available at: <https://www.sec.gov/comments/sr-cboebzx-2020-053/sr-cboebzx2020053.htm>.

⁹ 15 U.S.C. 78s(b)(2)(C).

¹⁰ 17 CFR 201.700(b)(3).

measures the daily performance of a theoretical portfolio of first- and second-month futures contracts on the Cboe Volatility Index (“VIX”).¹⁶ The Index is comprised of VIX futures contracts (“VIX Futures Contracts”).¹⁷

Specifically, the Index components represent the prices of the two near-term VIX Futures Contracts, replicating a position that rolls the nearest month VIX Futures Contract to the next month VIX Futures Contract on a daily basis in equal fractional amounts, resulting in a constant weighted average maturity of approximately one month.¹⁸ The Index seeks to reflect the returns that are potentially available from holding an unleveraged long position in first- and second- month VIX Futures Contracts by measuring its daily performance from the weighted average price of VIX Futures Contracts.¹⁹

To pursue its investment objective, the Fund will primarily invest in VIX Futures Contracts based on components of the Index. The Fund will primarily acquire long exposure to the VIX through VIX Futures Contracts, such that the Fund has exposure intended to approximate 200% of the return of the Index at the time of the net asset value (“NAV”) calculation of the Fund. However, in the event that the Fund is unable to meet its investment objective

¹⁶ The Exchange states that the VIX is an index designed to measure the implied volatility of the S&P 500 over 30 days in the future. *See* Amendment No. 2, *supra* note 3, at 4, n.4. The VIX is calculated based on the prices of certain put and call options on the S&P 500. *See id.* The VIX is reflective of the premium paid by investors for certain options linked to the level of the S&P 500. *See id.*

¹⁷ The Exchange states that VIX Futures Contracts are measures of the market’s expectation of the level of VIX at certain points in the future, and as such, will behave differently than current, or spot, VIX. *See id.* at 8. While the VIX represents a measure of the current expected volatility of the S&P 500 over the next 30 days, the prices of VIX Futures Contracts are based on the current expectation of what the expected 30-day volatility will be at a particular time in the future (on the expiration date). *See id.*

¹⁸ The Exchange states that the roll period usually begins on the Wednesday falling 30 calendar days before the S&P 500 option expiration for the following month (“Cboe VIX Monthly Futures Settlement Date”) and runs to the Tuesday prior to the subsequent month’s Cboe VIX Monthly Futures Settlement Date. *See id.* at 10.

¹⁹ The Exchange states that because VIX Futures Contracts correlate to future volatility readings of VIX, while the VIX itself correlates to current volatility, the Index and the Fund should be expected to perform significantly differently from the VIX over all periods of time. *See id.* at 9–10. Further, unlike the Index, the VIX, which is not a benchmark for the Fund, is calculated based on the prices of certain put and call options on the S&P 500. *See id.* at 10. According to the Exchange, while the Index does not correspond to the VIX, the value of the Index, and by extension the Fund, will generally rise as the VIX rises and fall as the VIX falls. *See id.* at 9.

solely through investment in VIX Futures Contracts, it may invest in over-the-counter swaps referencing the Index or referencing particular VIX Futures Contracts comprising the Index (“VIX Swap Agreements”) or in listed VIX options contracts (“VIX Options Contracts,” and, together with VIX Futures Contracts and VIX Swap Agreements, “VIX Derivative Products”). The Fund may also invest in Cash or Cash Equivalents,²⁰ which may serve as collateral to the Fund’s investments in VIX Derivative Products.

The Fund will seek to remain fully invested in VIX Derivative Products (and Cash and Cash Equivalents as collateral) that provide exposure to the Index consistent with its investment objective without regard to market conditions, trends or direction. The Fund’s investment objective is a daily investment objective; that is, the Fund seeks to track the Index on a daily basis, not over longer periods. Accordingly, each day, the Fund will position its portfolio so that it can seek to track the Index. The direction and extent of the Index’s movements each day will dictate the direction and extent of the Fund’s portfolio rebalancing. For example, if the level of the Index falls on a given day, net assets of the Fund would fall. As a result, exposure to the Index, through futures positions held by the Fund, would need to be decreased. The opposite would be the case if the level of the Index rises on a given day.

The time and manner in which the Fund will rebalance its portfolio is defined by the Index methodology but may vary from the Index methodology depending upon market conditions and other circumstances including the potential impact of the rebalance on the price of the VIX Futures Contracts. The Sponsor will seek to minimize the market impact of rebalances across all exchange traded products based on VIX Futures Contracts (“VIX ETPs”) that it sponsors (“Funds”) ²¹ on the price of

²⁰ “Cash and Cash Equivalents” are short-term instruments with maturities of less than 3 months, including the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers’ acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

²¹ For purposes of the filing, the Exchange states that the Funds include the Fund and the –1x Short

VIX Futures Contracts by limiting the Funds’ participation, on any given day, in VIX Futures Contracts to no more than 10% of the VIX Futures Contracts traded on Cboe Futures Exchange, Inc. (“CFE”) during any “Rebalance Period,” defined as any fifteen minute period of continuous market trading.²² To limit participation during periods of market illiquidity, the Sponsor, on any given day, may vary the manner and period over which all funds it sponsors are rebalanced, and as such, the manner and period over which the Fund is rebalanced. The Sponsor believes that the Fund will enter an Extended Rebalance Period most often during periods of extraordinary market conditions or illiquidity in VIX Futures Contracts. In the event that the Fund participates in an Extended Rebalance Period, the Fund represents that it will notify the Exchange and the Commission of such participation as soon as practicable, but no later than 9:00 a.m. ET on the trading day following the event.²³

III. Discussion and Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.²⁴ The Commission therefore approves the proposed rule change, as modified by Amendment Nos. 2 and 4.

The Commission received a number of comments letters addressing the proposed rule change’s consistency with the Act, specifically focusing on (1) the potential for systemic risks; and (2) investor protection concerns, in particular the potential risks posed to retail investors. The Commission addresses each of these issues below. In

VIX Futures ETF (“Short Fund”), but may in the future include additional VIX ETPs sponsored by the Sponsor or its affiliates. *See* Securities Exchange Act Release No. 93230 (Oct. 1, 2021) (SR–CboeBZX–2020–070) (“Short VIX Approval”).

²² In the event that the Funds expect to hit the 10% threshold during the primary Rebalance Period from 3:45 p.m. to 4:00 p.m. ET, the Funds will extend their respective rebalances into additional Rebalance Periods and the Trade at Settlement (“TAS”) market. It is expected that this extension will provide the Funds with the flexibility to: Begin rebalancing in an earlier period, end rebalancing in a later period, and execute contracts in TAS (each “an Extended Rebalance Period” and collectively “the Extended Rebalance Period”) while remaining below the 10% cap during any 15-minute period of continuous market trading. *See* Amendment No. 2, *supra* note 3, at 11–12, n.10. The Funds will be allocated executions based on their percentage of notional transaction volume required. *See id.* at 12.

²³ *See* Amendment No. 4, *supra* note 3, at 5.

²⁴ In approving this proposed rule change, the Commission has considered the proposed rule change’s impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

addition, in approving the listing and trading of the Shares, the Commission also analyzes the proposal to ensure there is an appropriate regulatory framework to support the listing and trading of the Shares. Finally, the Commission addresses the procedural argument that the proposed rule change has been deemed approved and is currently in effect.

The record demonstrates the proposal is reasonably designed to mitigate the market impact and investor protection concerns articulated in the OIP and raised by commenters, and that the Exchange has demonstrated that there is an appropriate regulatory framework to support the listing and trading of the Shares. Therefore, the Commission finds the proposal is consistent with the Act, in particular Section 6(b)(5).

A. Rebalance Design and Market Impact Considerations

Several of the commenters opposed to the proposal discuss the events of February 2018 as an example of the potential harm to retail investors and the potential systemic risk posed by volatility-linked exchange-traded products.²⁵ One commenter summarizes:

On February 5, 2018, after years of low market volatility, and accordingly a low VIX, the VIX doubled, a market event popularly known as “Volmageddon.” One inverted VIX exchange-traded product (“ETP”), known as the VelocityShares Daily Inverse VIX Short-Term note (“XIV”), shrank “from \$1.9 billion in assets to \$63 million in one session.”²⁶

The commenter further states that the nature of VIX ETPs “contributed directly to the market volatility” because these types of products must rebalance in order to ensure the appropriate exposure to the index.²⁷ Two commenters describe the rebalance as a “feedback loop,” because the issuer would have to purchase additional futures that would result in further declines for an inverse product.²⁸ According to one of the commenters, this feedback loop led to “all sorts of additional knock-effects for other market participants,” including declines

in major market indexes and investor losses in XIV.²⁹ A commenter states that each of the products proposed “involves the sort of rebalancing that exacerbated volatility during Volmageddon.”³⁰

The Sponsor also acknowledges that “[p]ast and existing VIX ETPs rebalance or roll their futures contracts according to a methodology linked to the VIX futures’ settlement each day.”³¹ Further, according to the Sponsor, daily settlement “has resulted in funds competing to execute their daily rebalance at a single point in time” resulting in “concentrated activity [that] erodes returns and may have contributed to at least one major market disruption.”³² It describes previous attempts to reduce this concentration by reducing the leverage of other existing inverse and leveraged VIX ETPs as having “slowed the progression of market crowding,” but concludes that these deleveraged products can still require “larger and larger rebalances at the same crowded settlement time” if they attract larger inflows.³³

The Sponsor further states that commenters arguing in favor of disapproval because of the failure of other VIX ETPs “miss a key point: lessons learned from the failures of previous products are at the very heart of the new methodology underlying [the proposed products].”³⁴ The Sponsor describes four ways the proposed products differ from previous and existing VIX ETPs: (1) The valuation is an average price over a longer time period instead of exclusively at the 4:00 p.m. ET settlement price; (2) a wider rebalancing period should distribute trading volume away from 4:00 p.m. ET, resulting in a more stable market; (3) the rebalance period may be extended to reduce market impact if required; and (4) the Sponsor has committed to a 10% participation cap for all VIX ETPs offered by the Sponsor.³⁵ The Sponsor states these differences should result in “an execution method that minimizes market impact and meaningfully lowers the chances of either [proposed product] experiencing a significant disruption”³⁶ and “less volatile products with

minimal impacts to the underlying VIX futures and the broader market.”³⁷

In its proposal, as modified by Amendment Nos. 2 and 4, the Exchange states that the Sponsor’s proposed methodology for the Funds seeks to reduce the dependence of VIX ETPs on TAS by seeking to execute part of the Funds’ daily rebalance outside of TAS and believes that this approach will spread VIX futures trading activity over a longer period of time each day and should help to reduce market impact during periods of market turmoil or disruption.³⁸ In addition, the Exchange states that the Sponsor expects that allowing the Funds to participate in an Extended Rebalance Period will minimize the impact of the Funds’ rebalance on the price of VIX Futures Contracts, and particularly minimize any impact of large rebalances during periods of market illiquidity.³⁹ The Exchange further states that “the rebalancing mechanism to be used by the Funds is designed to reduce the Funds’ individual and collective impact on the volatility market and the associated potentially negative impact on the Funds.”⁴⁰

In its assessment of the proposal, the Commission considered the potential for market disruption during periods with large percentage increases in volatility and, because of the potential for large, sudden moves in VIX levels, the potential for large spikes in rebalancing demand for VIX ETPs. As commenters note, the events of February 2018 occurred during a period when volatility had been relatively low and spiked, as the spot price of VIX more than doubled, and there was a large spike in the trading volume in VIX futures contracts at the end of day. A portion of the volume was attributable to the rebalancing demand of volatility-linked ETPs.

In the OIP, the Commission requested comment on the Fund’s operation during periods with large percentage increases in volatility and the potential market impact of the Fund’s daily rebalance.⁴¹ Following the OIP, the Exchange amended its proposal to state that the Sponsor will seek to minimize the market impact of rebalances across all Funds on the price of VIX Futures

²⁵ See letters from Americans for Financial Reform Education Fund, dated May 7, 2021 (“AFREF”); Dennis M. Kelleher, President and CEO; Stephen Hall, Legal Director and Securities Specialist; and Jason Grimes, Senior Counsel, Better Markets, Inc., dated May 7, 2021 (“Better Markets”); Tyler Gellach, Executive Director, Healthy Markets Association, dated May 7, 2021 (“Healthy Markets”); and Robert Rutkowski, dated May 10, 2021 (“Rutkowski”).

²⁶ Better Markets at 2.

²⁷ See Better Markets at 2.

²⁸ See Better Markets at 3 (citing Patrick Augustin, et al., *Volmageddon and the Failure of Short Volatility Products* (Apr. 6, 2021, *Financial Analysts Journal*, Forthcoming)); and AFREF at 3.

²⁹ AFREF at 3–4.

³⁰ Better Markets at 3.

³¹ Letter from Barry I. Pershkov, Partner, Chapman and Cutler LLP, on behalf of the Sponsor, dated May 7, 2021 (“Volatility Shares 1”) at 2.

³² Volatility Shares 1 at 2.

³³ See Volatility Shares 1 at 2.

³⁴ See letter from Stuart Barton, Chief Investment Officer, Sponsor, dated May 19, 2021 (“Volatility Shares 2”) at 2.

³⁵ Volatility Shares 1 at 3.

³⁶ Volatility Shares 1 at 3.

³⁷ Volatility Shares 2 at 2.

³⁸ See Amendment No. 2, *supra* note 3, at 12. Commenters writing in support of SR–CboeBZX–2020–070 also described the potential benefits of the rebalance design. See Short VIX Approval, *supra* note 21, at nn. 38–42 and accompanying text.

³⁹ See Amendment No. 4, *supra* note 3, at 4.

⁴⁰ Letter from Kyle Murray, Vice President, Associate General Counsel, Cboe Global Markets, dated May 7, 2021 (“BZX Letter”) at 2.

⁴¹ See OIP, *supra* note 3, 85 FR at 64565.

Contracts by limiting the Funds' participation, on any given day, in VIX Futures Contracts to no more than ten percent of the VIX Futures Contracts traded on CFE during any Rebalance Period.⁴²

The Exchange's proposal regarding the rebalancing methodology of the Fund serves as an appropriate limit on the Fund's participation in the VIX futures market, and is reasonably designed to help mitigate the potential market impact on the Fund's daily rebalance demand during periods when there are large percentage increases in volatility.⁴³ In discussing the events of "Volmageddon," commenters describe several factors that may have contributed to the spike in futures prices: (1) Growing assets under management ("AUM") for VIX ETPs, which in turn required more rebalancing; (2) a large percentage increase in volatility; and (3) a market where multiple funds were attempting to rebalance simultaneously, and where the VIX futures TAS market was halted "limit up."⁴⁴ The design of the rebalancing methodology helps to mitigate the first and third factors, even if there is a large percentage increase in volatility. Because the Funds' must limit their participation in any Rebalance Period to 10%, the participation cap still serves as a limit on the Funds' rebalancing demand during each Rebalance Period, regardless of AUM. Further, the Funds' rebalance is spread over a longer time period and distributes trading away from a single point in time when other funds may be rebalancing,⁴⁵ and permits the Funds' limited flexibility in order to reduce market impact, which may help reduce market crowding. In addition, the Commission observes that the VIX futures market has changed since the events of "Volmageddon:" (1) TAS has

⁴² See Amendment No. 2, *supra* note 3, at 11. In its original proposal, the Exchange did not include a participation limitation.

⁴³ A commenter states that the Commission should not view individual product proposals in isolation. See Better Markets at 6. Although the Commission's findings in this order are based on the specific proposed rule change filed with the Commission, including how the proposed rule operates under the current market conditions discussed in this order, the Commission recognizes that, over time, market conditions in VIX ETP markets, and the related VIX futures market, may change.

⁴⁴ See letter from Stuart Barton, Head of Investments, Sponsor, dated January 6, 2021, at n. 1. This letter was submitted to the comment file for SR-CboeBZX-2020-070 and is available at: <https://www.sec.gov/comments/sr-cboebzx-2020-070/sr-cboebzx2020070.htm>.

⁴⁵ For example, two existing leveraged VIX ETPs target a 4 p.m. ET benchmark. See Securities Exchange Act Release No. 90691 (Dec. 16, 2020), 85 FR 83643 (Dec. 22, 2020) (SR-CboeBZX-2020-093).

a wider permissible price range;⁴⁶ and (2) VIX futures settle at 4:00 p.m. ET rather than 4:15 p.m. ET (*i.e.*, after the close of U.S. equity market trading).⁴⁷

In sum, the Commission considered the potential that VIX ETPs might have a destabilizing effect on markets during times of market stress. Based on the record, including commenters' descriptions of the events of February 2018, the Commission concludes that the Exchange's proposal is reasonably designed to help mitigate against the market impact concerns articulated in the OIP and by commenters opposed to the proposal. The rebalance design of the Funds may help distribute rebalancing volume. Further, the 10% participation cap strikes an appropriate balance between allowing the Funds to rebalance within a reasonably short period of time and managing the potential market impact of a large rebalance. Therefore, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act, including the protection of investors and the public interest.

B. Investor Protection

Commenters also raise concerns about the risks and complexity of leveraged and inverse VIX ETPs and their suitability for retail investors. One of the commenters asserts that: (1) Recent market events and the public record with the VIX raise significant questions about the investor-protection risks posed by VIX-related investment products; (2) such questions must be adequately addressed by filings to list and trade more VIX-related products; and (3) the Exchange has not explained how explain how its proposed listing and trading of the Shares would be consistent with the Act, including the protection of investors.⁴⁸ Another commenter states that the absence of new sales practices protections for leveraged investment products "leaves investors with extremely inadequate protections in this space."⁴⁹ According to the commenter, shares of leveraged exchange-traded funds are unsuitable for retail investors because they provide

⁴⁶ See Choe Product Update, "Price Parameter Change for TAS Transactions in VX Futures," 2018, available at: https://cdn.cboe.com/resources/product_update/2018/VX-Trade-at-Settlement-VXT-Price-Parameter-Change.pdf.

⁴⁷ See Choe Futures Exchange, LLC Rule Certification, Submission Number CFE-2020-028 (September 23, 2020), available at: https://cdn.cboe.com/resources/regulation/rule_filings/pending/2020/20-028-Daily-Settlement-Determination-Time.pdf#:~:text=The%20Daily%20Settlement%20Time%20for%20VX%20futures%20is,for%20VX%20futures%20is%203%3A00%20p.m.%20Chicago%20time.

⁴⁸ See Healthy Markets at 6.

⁴⁹ AFREF at 1-2.

markedly different returns—and generally significantly underperform—their underlying indices over the long-term.⁵⁰ That commenter also asserts that it would be inconsistent with the protection of investors to facilitate gambling-like market practices by approving additional products that enable leveraged bets on synthetic indexes.⁵¹ More specifically, the commenter states that the Shares would not directly support economic activity and, in the commenter's view, the assertion that any hedging achieved through the Shares would lead to a net gain in real capital formation is not supported.⁵² Another commenter also states that the product has no purpose beyond the issuer "invit[ing] speculative gamblers" so that it can profit off of management expenses.⁵³ Commenters also state that the products are inconsistent with the Act because there are "inherent dangers" for leveraged exchange-traded products that make them unsuitable for retail investors.⁵⁴ Finally, one commenter states that the Approval Order does not adequately address the risks to investors and to retail investors in particular.⁵⁵

In response, the Sponsor states that commenters' concerns related to leveraged and inverse exchange-traded products, and in particular the concern that such products underperform their benchmarks over time, have been raised previously. It states that such products are not designed to perform over long periods of time, and that courts have "affirmed the adequacy of the disclosure contained in the registration statement of these products."⁵⁶ In addition, the Exchange states that the proposed products would provide "investors with new tools to implement investment strategies to which they might not otherwise have access."⁵⁷ The Sponsor

⁵⁰ See AFREF at 2. Another commenter asserts that certain investors purchasing the Shares may "be surprised to see that their losses would be amplified by a factor of 2 during periods of low volatility" and, in the view of this commenter, both products raise investor protection concerns because they are "complex and risky." See Better Markets at 4-5. A commenter provides annual returns for another leveraged volatility product and asserts it is "almost impossible to make money long side, even for short-term." See letter from John Motson, dated July 10, 2020 ("Motson").

⁵¹ See AFREF at 2.

⁵² See AFREF at 3.

⁵³ Motson.

⁵⁴ See Rutkowski, Healthy Markets at 2-3.

⁵⁵ See Better Markets at 4-5.

⁵⁶ Volatility Shares 2 at 1-2.

⁵⁷ BZX Letter at 2. The Exchange states that the Funds would provide greater short and long exposure than ETPs currently trading on U.S. exchanges. See *id.* In addition, commenters writing in support of the Short Fund state that the product would fulfill a need in the ETP space by permitting certain investors to obtain short volatility exposure

also cites the Commission's recent amendments to Rule 6c-11 of the Investment Company Act of 1940, which would include certain leveraged and inverse exchange-traded funds within the scope of Rule 6c-11, as well as the Commission's approvals of leveraged and inverse exchange-traded products that are not registered investment companies.⁵⁸ The Sponsor asserts that this demonstrates that questions related to leveraged and inverse products have been therefore "asked and answered."⁵⁹

The Commission acknowledges commenters' concerns, but believes this proposed rule change is consistent with the protection of investors. Commenters assert that the Exchange has not met its burden to demonstrate the proposal is consistent with the protection of investors because leveraged and inverse exchange-traded products, in particular those linked to volatility, are complex and risky, and underperform their benchmarks over time. The Commission has recognized that certain complex products, such as inverse or leveraged exchange-traded products, "which may be useful for some sophisticated trading strategies, are highly complex financial instruments and are typically designed to achieve their stated objectives on a daily basis."⁶⁰ However, there are existing rules and standards of conduct applicable to other complex products that would apply to listing and trading of the Shares. The best interest standard of conduct for broker-dealers required under Regulation Best Interest and the fiduciary obligations of investment advisers discussed in the Fiduciary Interpretation thereto apply to transactions in all exchange-traded products where the transaction is recommended by a broker-dealer or pursuant to the advice of an investment adviser.⁶¹ In addition, the Financial Industry Regulatory Authority ("FINRA") has implemented increased sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged and inverse leveraged securities (which include the Shares), and has provided specific guidance regarding sales

in a more efficient manner than is currently available. See Short VIX Approval, *supra* note 21, nn. 60-62 and accompanying text.

⁵⁸ See Volatility Shares 2 at 1-2.

⁵⁹ Volatility Shares 2 at 1-2.

⁶⁰ Regulation Best Interest Adopting Release, Exchange Act Rel. No. 86031 (Jun. 5, 2019), 84 FR 33318 (Jul. 12, 2019), at 33376.

⁶¹ See Investment Company Act Rel. No. 34084, (Nov. 2, 2020), 85 FR 83217 (Dec. 21, 2020), at 83217-18 (discussing the best interest standard of conduct for broker-dealers and the fiduciary obligations of investment advisers in the context of all exchange-traded products).

practice obligations for volatility-linked exchange-traded products.⁶² Exchange members that carry customer accounts will be required to follow the FINRA guidance set forth in these notices. The Exchange also has rules relating to suitability, in particular BZX Rule 3.7.⁶³ Therefore, the Commission finds that this proposal is consistent with the Act, in particular the protection of investors and the public interest.⁶⁴

C. Other Considerations

In addition, the Commission analyzed other aspects of the Exchange's proposal and finds, as explained below, that the proposal is consistent with the Act because it is designed to prevent fraudulent and manipulative acts and practices and protect investors and the public interest. The Exchange has demonstrated there is an appropriate regulatory framework to support listing and trading of the Shares, including trading rules, surveillance, and listing standards.

The proposal is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading in the Shares when a reasonable degree of certain pricing transparency cannot be assured. Specifically, the Exchange will obtain a representation from the Sponsor of the Shares that the NAV will be calculated daily and that the NAV and the Fund's holdings will be made available to all market participants at the same time. On each Business Day,⁶⁵ before commencement of trading in Shares

⁶² See FINRA Regulatory Notices 09-31 (Jun. 2009), 09-53 (Aug. 2009), 09-65 (Nov. 2009), 12-03 (Jan. 2012), and 17-32 (Oct. 2017).

⁶³ In particular, Rule 3.7 imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers and Interpretation and Policy .01 of BZX Rule 3.7 imposes a duty of due diligence on Exchange members to learn the essential facts relating to every customer prior to trading the Shares, and specifically provides that "[n]o Member shall recommend to a customer a transaction in any such product unless the Member has a reasonable basis for believing at the time of making the recommendation that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks of the recommended transaction and is financially able to bear the risks of the recommended position."

⁶⁴ Although the Commission finds the proposal is consistent with the Exchange Act, the Commission is not expressing a view about whether the Shares are appropriate or suitable for all investors.

⁶⁵ A "Business Day" means any day other than a day when any of BZX, Cboe, CFE or other exchange material to the valuation or operation of the Fund, or the calculation of the VIX, options contracts underlying the VIX, VIX Futures Contracts or the Index is closed for regular trading.

during Regular Trading Hours,⁶⁶ the Fund will disclose on its website the holdings that will form the basis for the Fund's calculation of NAV at the end of the Business Day. This website disclosure of the portfolio composition of the Fund will occur at the same time as the disclosure by the Fund of the portfolio composition to authorized participants, so that all market participants will be provided portfolio composition information at the same time, and the same portfolio information will be provided on the public website as in electronic files provided to authorized participants. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association. As required by BZX Rule 14.11(f)(4), an updated Intraday Indicative Value ("IIV") will be calculated and widely disseminated by one or more major market data vendors every 15 seconds throughout Regular Trading Hours. The IIV will be published on the Exchange's website and will be available through on-line information services such as Bloomberg and Reuters. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The Fund's website will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. In addition, the level of the Index will be published at least every 15 seconds in real time from 9:30 a.m. to 4:00 p.m. ET and at the close of trading on each Business Day by Bloomberg and Reuters.

Quotation and last-sale information regarding VIX Futures Contracts and VIX Options Contracts will be available from the exchanges on which such instruments are traded. Quotation and last-sale information relating to VIX Options Contracts will also be available via the Options Price Reporting Authority. Quotation and last-sale information for VIX Swap Agreements will be available from nationally recognized data services providers, such as Reuters and Bloomberg, through subscription agreements or from a broker-dealer who makes markets in such instruments. Pricing information regarding Cash Equivalents in which the Fund may invest is generally available through nationally recognized data services providers, such as Reuters and Bloomberg, through subscription

⁶⁶ As defined in BZX Rule 1.5(w), the term "Regular Trading Hours" means the time between 9:30 a.m. and 4:00 p.m. ET.

agreements. The closing prices and settlement prices of the Index Components (*i.e.*, the first- and second-month VIX Futures Contracts) will be readily available from the websites of CFE (<http://www.cfe.cboe.com>), automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. The CFE also provides delayed futures information on current and past trading sessions and market news free of charge on its website. Complete real-time data for component VIX Futures Contracts underlying the Index, including the specific contract specifications of Index Components (*i.e.*, first-month and second-month VIX Futures Contracts), is available by subscription from Reuters and Bloomberg.

The Exchange's rules regarding trading halts further help to ensure the maintenance of fair and orderly markets for the Shares, which is consistent with the protection of investors and the public interest. Trading in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the daily disclosed portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, the Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18 (Trading Halts Due to Extraordinary Market Volatility). BZX Rule 14.11(f)(4)(c)(ii) enumerates additional circumstances under which the Exchange will consider the suspension of trading in and will commence delisting proceedings for the Shares.

The Exchange's proposal is designed to safeguard material non-public information relating to the Fund's portfolio. Specifically, as the Exchange states, the Sponsor is not a broker-dealer or affiliated with a broker-dealer. In the event that (a) the Sponsor becomes a broker-dealer or newly affiliated with a broker-dealer, or (b) any new sponsor is a broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the

portfolio. Moreover, trading of the Shares will be subject to BZX Rule 14.11(f)(4)(D), which sets forth certain restrictions on Exchange members acting as registered Market Makers⁶⁷ in Trust Issued Receipts to facilitate surveillance. In addition, the Exchange has a general policy prohibiting the distribution of material, non-public information by its employees.

Furthermore, the Exchange or FINRA, on behalf of the Exchange, or both, will communicate and may obtain information regarding trading in the Shares and the underlying listed instruments, including listed derivatives held by the Fund, with the Intermarket Surveillance Group ("ISG"), other markets or entities who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. The trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, and these procedures are adequate to properly monitor Exchange trading of the Shares during all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. In addition, all of the VIX Futures Contracts and VIX Options Contracts held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Moreover, the trading of the Shares on the Exchange will be subject to the Exchange's and other rules listed below. Specifically:

(1) The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities;

(2) The Shares will conform to the initial and continued listing criteria under BZX Rule 14.11(f);

(3) Pursuant to BZX Rule 14.11(a), all statements and representations made in the filing regarding the Index composition, description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of the Index, reference assets, and IIV, or the applicability of Exchange listing rules specified in the filing shall constitute continued listing requirements for the Shares. The issuer will advise the Exchange of any failure by the Fund to comply with the continued listing

⁶⁷ As defined in BZX Rule 1.5(l), the term "Market Maker" means an Exchange member that acts as a Market Maker pursuant to Chapter XI of the BZX Rules.

requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

(4) The Exchange has the appropriate rules to facilitate transactions in the Shares during all trading sessions;

(5) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares;⁶⁸

(6) FINRA has implemented increased sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged and inverse leveraged securities (which include the Shares) and options on such securities, as described in FINRA Regulatory Notices 09-31 (June 2009), 09-53 (August 2009), and 09-65 (November 2009). Exchange members that carry customer accounts will be required to follow the FINRA guidance set forth in these notices;

(7) For initial and continued listing, the Fund and the Trust must be in compliance with Rule 10A-3 under the Act;⁶⁹ and

(8) A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

D. Procedural Considerations

The Sponsor also asserts that the proposed rule change has been deemed

⁶⁸ The Exchange states that the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (c) Interpretation and Policy .01 of BZX Rule 3.7 which imposes a duty of due diligence on its members to learn the essential facts relating to every customer prior to trading the Shares, and specifically provides that "[n]o Member shall recommend to a customer a transaction in any such product unless the Member has a reasonable basis for believing at the time of making the recommendation that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks of the recommended transaction and is financially able to bear the risks of the recommended position;" (d) how information regarding the IIV and the Fund's holdings is disseminated; (e) the risks involved in trading the Shares during the Pre-Opening and After Hours Trading Sessions (as such terms are defined in BZX Rules) when an updated IIV will not be calculated or publicly disseminated; (f) the requirement that Exchange members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (g) trading information.

⁶⁹ 17 CFR 240.10A-3.

approved pursuant to Exchange Act Section 19(b)(2)(D)(ii).⁷⁰ The Commission disagrees with the Sponsor's assertions that: (1) Because the Approval Order is stayed, "the Commission did not effectively approve or disapprove [the Proposal] by the 240th day" and therefore the proposal has been deemed approved;⁷¹ and (2) the Commission's discretionary review of the order by delegated authority conflicts with the purpose and language of the statute.⁷²

The Commission complied with the requirements of the statute. Section 19(b)(2)(D) requires only that the Commission "issue an order" approving or disapproving the proposed rule change within 240 days. The Approval Order was issued within that period.

Although orders issued by delegated authority are issued by Commission staff, they are issued with the full authority of the Commission and are signed by the Secretary's office on behalf of the Commission. Section 4A of the Exchange Act authorizes the Commission to delegate certain functions—including approval or disapproval of proposed rule changes under Section 19—to a "division of the Commission."⁷³ And the Commission's Rules of Practice make clear that "an action made pursuant to delegated authority shall have immediate effect and be deemed the action of the Commission."⁷⁴

⁷⁰ See Volatility Shares 1 at 4. Section 19(b) of the Exchange Act requires the Commission to "issue an order" approving or disapproving a proposed rule change within, at most, 240 days of the proposed rule change's filing. See 15 U.S.C. 78s(b)(2)(B)(ii). If the Commission fails to issue an order within that period, the proposed rule change is deemed to have been approved. See 15 U.S.C. 78s(b)(2)(D).

⁷¹ See Volatility Shares 1 at 4. The Sponsor cites this proposal as having been deemed approved since the relevant period had not yet elapsed for CboeBZX-2020-070 when it made its argument. It states that CboeBZX-2020-070 would also be deemed approved unless the Commission acted by May 21, 2021.

⁷² See Volatility Shares 1 at 2.

⁷³ 15 U.S.C. 78d-1(a).

⁷⁴ Commission Rule of Practice 431(e), 17 CFR 201.431(e). See also, e.g., Rule of Practice 430(c), 17 CFR 201.430(c) (referring to "a final order entered pursuant to [delegated authority]"); Rule of Practice 431(f), 17 CFR 201.431(f) (giving an order by delegated authority operative effect, even when review has been sought, until a person receives actual notice that it was been stayed, modified, or reversed on review). Moreover, as the Commission has previously explained, Congress was aware of the Commission's ability to delegate authority to approve SRO rule filings when the time restrictions in Exchange Act Section 19(b)(2)(D) were enacted. And to construe Section 19(b)(2), as the Sponsor does, to require Commission review of an order by delegated authority to be completed within 240 days "would undermine both the specific deadlines set forth in the statute and the Commission's ability to delegate functions. Nor is such a construction necessary to fulfill Congress's purpose in enacting the deadlines to "streamline" the rule filing

IV. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.

It is therefore ordered, pursuant to Rule 431 of the Commission's Rules of Practice, that the earlier action taken by delegated authority, Securities Exchange Act Release No. 91265 (March 5, 2021), 86 FR 13922 (March 11, 2021), is set aside and, pursuant to Section 19(b)(2) of the Act, the proposed rule change (SR-CboeBZX-2020-053), as modified by Amendment Nos. 2 and 4, hereby is approved.

By the Commission.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21880 Filed 10-6-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93236; File No. SR-ICEEU-2021-018]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Collateral and Haircut Procedures

October 1, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 20, 2021, ICE Clear Europe Limited ("ICE Clear Europe" or the "Clearing House") filed with the Securities and Exchange Commission ("Commission") the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

process. With rare exception, rule filings are decided, by delegated authority or otherwise, within 240 days. See Securities Exchange Act Release Nos. 88493 (Mar. 27, 2020), 85 FR 18617 (Apr. 2, 2020) (Order Affirming Action by Delegated Authority and Disapproving Proposed Rule Changes Related to Connectivity and Port Fee in the Matter BOX Exchange LLC) at 18626; and 82727 (Feb. 15, 2018), 83 FR 7793 (Feb. 22, 2017) (Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, Regarding the Acquisition of CHX Holdings, Inc. by North America Casin Holdings, Inc.) at 7799.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed amendments is for ICE Clear Europe to modify its Collateral and Haircut Procedures (the "Collateral and Haircut Procedures" or "Procedures") to (i) include explicitly the formula used for calculating Permitted Cover value, and (ii) provide further details on the Clearing House's procedures for monitoring data related to collateral valuations, including the responsibilities of its different teams.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) *Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

(a) Purpose

ICE Clear Europe is proposing to revise the Collateral and Haircut Procedures to state explicitly the formula used by the Clearing House for calculating the value of Permitted Cover provided by Clearing Members in respect of margin and guaranty fund requirements. The formula would provide that cover value is equal to $\text{Nominal} * \text{Price} / 100 * (1 - \text{Haircut}) + \text{Nominal} * \text{Accrued}$, where price is clean and accrued is expressed in %. Further to this description of the Permitted Cover value calculation, the changes would also state that as a matter of standard practice at the Clearing House, Treasuries would be given no cover value 2 business days prior to maturity and a cash call would be issued if a Member's account is in deficit. Additionally, the amendments would state that accrued interest would lose value one day prior to the coupon pay date. These changes reflect existing practice at ICE Clear Europe with respect to the valuation of Permitted Cover and are intended only to document that practice more clearly.

The amendments would also update the Clearing House's processes for monitoring data related to collateral pricing and would describe the roles of

various teams tasked with such monitoring. Specifically, the amendments would reflect that the System Operations team checks end of day collateral pricing. The amendments would state that the Credit team has the controls to monitor End of Day market data that the System Operations team uses to value collateral against thresholds to ensure that the data is not “stale”. Additionally, the amendment would provide that the Treasury team reconciles and confirms the daily bilateral collateral positions (nominal amounts). These amendments would not reflect a change in current practice, but are intended to clarify relevant documentation.

Finally, the description of the scope of the Collateral and Haircut Procedures would be revised to remove an incorrect statement that the Procedures do not address intraday and end of day valuation of collateral.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments to the Collateral and Haircut Procedures are consistent with the requirements of Section 17A of the Act³ and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(F) of the Act⁴ requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

The proposed changes to the Procedures are designed to clarify the documentation of certain existing practices of the Clearing House around valuation of Permitted Cover. Specifically, the amendments would update and clarify the processes, controls and escalations with respect to collateral valuation data monitoring as well as outline the responsibilities of the Clearing House’s teams in relation to such monitoring. They would also state the formula used by the Clearing House for calculating Permitted Cover value. The amendments would thus facilitate the operation of the Clearing House’s margin framework and overall risk management procedures, and thereby promote the stability of the Clearing House and the prompt and accurate clearance and settlement of cleared contracts. The amendments are for these

reasons also generally consistent with the protection of investors and the public interest in the safe operation of the Clearing House. (ICE Clear Europe would not expect the amendments to affect the safeguarding of securities and funds in ICE Clear Europe’s custody or control or for which it is responsible.) Accordingly, the amendments satisfy the requirements of Section 17A(b)(3)(F).⁵

The amendments to the Collateral and Haircut Procedures are also consistent with relevant provisions of Rule 17Ad–22. Rule 17Ad–22(e)(5) requires the clearing agency to “set and enforce appropriately conservative haircuts and concentration limits if [it] requires collateral to manage its or its participants’ credit exposure.”⁶ Rule 17Ad–22(e)(6)(iv)⁷ requires clearing agencies to maintain a risk-based margin model that, among other things, “uses reliable sources of timely price data and uses procedures and sound valuation models for addressing circumstances in which pricing data are not readily available or reliable” The amendments would clarify the documentation of the Clearing House’s procedures for valuing collateral and monitoring relevant valuation and pricing data. As such, the amendments are consistent with the requirements of Rule 17Ad–22.

Rule 17Ad–22(e)(2)⁸ requires clearing agencies to establish reasonably designed policies and procedures to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. The amendments to the Collateral and Haircut Procedures would clarify the responsibilities of the Clearing House’s teams in relation to collateral valuation data monitoring. In ICE Clear Europe’s view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(2).⁹

(B) Clearing Agency’s Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments are being adopted to update the Clearing House’s Collateral and Haircut Procedures, which describe the Clearing House’s internal processes for collateral and haircut risk management as

presented in the ICE Clear Europe’s Collateral and Haircut Policy. The amendments are intended to more clearly document certain valuation practices and are not intended to change Clearing House practices. ICE Clear Europe does not believe the amendments would affect the costs of clearing, the ability to market participants to access clearing, or the market for clearing services generally. Therefore, ICE Clear Europe does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change and adoption.

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–ICEEU–2021–018 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.

⁵ 15 U.S.C. 78q–1(b)(3)(F).

⁶ 17 CFR 240.17Ad–22(e)(5).

⁷ 17 CFR 240.17Ad–22(e)(6)(iv).

⁸ 17 CFR 240.17Ad–22(e)(2).

⁹ 17 CFR 240.17Ad–22(e)(2).

³ 15 U.S.C. 78q–1.

⁴ 15 U.S.C. 78q–1(b)(3)(F).

All submissions should refer to File Number SR–ICEEU–2021–018. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe’s website at <https://www.theice.com/clear-europe/regulation>.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2021–018 and should be submitted on or before October 28, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21866 Filed 10–6–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93230; File No. SR–CboeBZX–2020–070]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Setting Aside Action by Delegated Authority and Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 3, To List and Trade Shares of the –1x Short VIX Futures ETF Under BZX Rule 14.11(f)(4) (Trust Issued Receipts)

October 1, 2021.

I. Introduction

On September 4, 2020, Cboe BZX Exchange, Inc. (“BZX”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act” or “Exchange Act”) ¹ and Rule 19b–4 thereunder,² a proposed rule change to list and trade shares (“Shares”) of the –1x Short VIX Futures ETF (“Fund”), a series of VS Trust (“Trust”), under BZX Rule 14.11(f)(4).³

On March 5, 2021, the Commission, acting through authority delegated to the Division of Trading and Markets (“Division”),⁴ noticed the filing of Amendment Nos. 1 and 3 and approved the proposed rule change, as modified by Amendment Nos. 1 and 3, on an accelerated basis.⁵ On March 5, 2021, the Assistant Secretary of the Commission notified BZX that, pursuant to Commission Rule of Practice 431,⁶ the Commission would review the Division’s action pursuant to delegated authority and that the Division’s action pursuant to delegated authority was

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ The proposed rule change was published for comment in the *Federal Register* on September 23, 2020. See Securities Exchange Act Release No. 89901 (Sept. 17, 2020), 85 FR 59836 (“Notice”). On October 30, 2020, the Commission extended the time period for Commission action on the proposed rule change. See Securities Exchange Act Release No. 90292, 85 FR 70678 (Nov. 5, 2020). On December 14, 2020, the Commission instituted proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether to approve or disapprove the proposed rule change. See Securities Exchange Act Release No. 90659, 85 FR 82536 (Dec. 18, 2020) (“OIP”). On January 28, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed. On February 16, 2021, the Exchange submitted Amendment No. 2 to the proposed rule change and, on February 19, 2021, the Exchange withdrew Amendment No. 2. On February 19, 2021, the Exchange filed partial Amendment No. 3 to the proposed rule change.

⁴ 17 CFR 200.30–3(a)(12).

⁵ See Securities Exchange Act Release No. 91264 (Mar. 5, 2021), 86 FR 13939 (Mar. 11, 2021) (“Approval Order”).

⁶ 17 CFR 201.431.

stayed until the Commission ordered otherwise.⁷ On April 7, 2021, the Commission issued a scheduling order, pursuant to Commission Rule of Practice 431, providing until May 7, 2021 for any party or other person to file a written statement in support of, or in opposition to, the Approval Order.⁸

The Commission has conducted a *de novo* review of BZX’s proposal, giving careful consideration to the entire record, including all comments and statements submitted, to determine whether the proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. Under Section 19(b)(2)(C) of the Act, the Commission must approve the proposed rule change of a self-regulatory organization (“SRO”) if the Commission finds that the proposed rule change is consistent with the requirements of the Act and the applicable rules and regulations thereunder; if it does not make such a finding, the Commission must disapprove the proposed rule change.⁹ Additionally, under Rule 700(b)(3) of the Commission’s Rules of Practice, the “burden to demonstrate that a proposed rule change is consistent with the Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change.”¹⁰ The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding.¹¹ Any failure of a self-regulatory organization to provide the information required by Rule 19b–4 and elicited on Form 19b–4 may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the rules and regulations thereunder that are applicable to the self-regulatory organization.¹²

For the reasons discussed further herein, BZX has met its burden to show

⁷ See letter from J. Matthew DeLesDernier, Assistant Secretary, Commission, to Kyle Murray, Vice President and Associate General Counsel, Cboe Global Markets, dated March 5, 2021, available at <https://www.sec.gov/rules/sro/cboebzx/2018/34-91264-letter-from-assistant-secretary.pdf>.

⁸ See Securities Exchange Act Release No. 91502, 86 FR 19298 (Apr. 13, 2021). Comments on the proposed rule change, including statements concerning the Approval Order are available at: <https://www.sec.gov/comments/sr-cboebzx-2020-070/srcboebzx2020070.htm>.

⁹ 15 U.S.C. 78s(b)(2)(C).

¹⁰ 17 CFR 201.700(b)(3).

¹¹ See *id.*

¹² See *id.* See also 17 CFR 240.19b–4.

¹⁰ 17 CFR 200.30–3(a)(12).

that the proposed rule change is consistent with the Act, and this order sets aside the Approval Order and approves BZX's proposed rule change, as modified by Amendment Nos. 1 and 3. In particular, the Commission concludes that the record before the Commission demonstrates that BZX's proposal is consistent with Section 6(b)(5) of the Act,¹³ which requires that the rules of a national securities exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

II. Summary of the Proposal

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(f)(4), which governs the listing and trading of Trust Issued Receipts¹⁴ on the Exchange. Volatility Shares LLC ("Sponsor") serves as the Sponsor of the Trust. The Fund's investment objective is to provide daily investment results (before fees and expenses) that correspond to the performance of the Short VIX Futures Index (SHORTVOL) ("Index"),¹⁵ which measures the daily inverse performance of a theoretical portfolio of first- and second-month futures contracts on the Cboe Volatility Index ("VIX").¹⁶ The Index is comprised of VIX futures contracts ("VIX Futures Contracts").¹⁷ Specifically, the Index

components represent the prices of the two near-term VIX Futures Contracts, replicating a position that rolls the nearest month VIX Futures Contract to the next month VIX Futures Contract on a daily basis in equal fractional amounts, resulting in a constant weighted average maturity of approximately one month.¹⁸ The Index seeks to reflect the returns that are potentially available from holding an unleveraged short position in first- and second- month VIX Futures Contracts by measuring its daily performance from the weighted average price of VIX Futures Contracts.¹⁹

To pursue its investment objective, the Fund will primarily invest in VIX Futures Contracts based on components of the Index. The Fund will primarily acquire short exposure to the VIX through VIX Futures Contracts, such that the Fund has exposure intended to approximate the Index at the time of the net asset value ("NAV") calculation of the Fund. However, in the event that the Fund is unable to meet its investment objective solely through investment in VIX Futures Contracts, it may invest in over-the-counter swaps referencing the Index or referencing particular VIX Futures Contracts comprising the Index ("VIX Swap Agreements") or in listed VIX options contracts ("VIX Options Contracts," and, together with VIX Futures Contracts and VIX Swap Agreements, "VIX Derivative Products"). The Fund may also invest in Cash or Cash Equivalents,²⁰ which may

See id. at 8. While the VIX represents a measure of the current expected volatility of the S&P 500 over the next 30 days, the prices of VIX Futures Contracts are based on the current expectation of what the expected 30-day volatility will be at a particular time in the future (on the expiration date). *See id.*

¹⁸ The Exchange states that the roll period usually begins on the Wednesday falling 30 calendar days before the S&P 500 option expiration for the following month ("Cboe VIX Monthly Futures Settlement Date") and runs to the Tuesday prior to the subsequent month's Cboe VIX Monthly Futures Settlement Date. *See id.* at 10.

¹⁹ The Exchange states that because VIX Futures Contracts correlate to future volatility readings of VIX, while the VIX itself correlates to current volatility, the Index and the Fund should be expected to perform significantly differently from the inverse of the VIX over all periods of time. *See id.* at 9–10. Further, unlike the Index, the VIX, which is not a benchmark for the Fund, is calculated based on the prices of certain put and call options on the S&P 500. *See id.* at 10. According to the Exchange, while the Index does not correspond to the inverse of the VIX, because it seeks short exposure to VIX, the value of the Index, and by extension the Fund, will generally rise as the VIX falls and fall as the VIX rises. *See id.* at 9.

²⁰ "Cash and Cash Equivalents" are short-term instruments with maturities of less than 3 months, including the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which

serve as collateral to the Fund's investments in VIX Derivative Products.

The Fund will seek to remain fully invested in VIX Derivative Products (and Cash and Cash Equivalents as collateral) that provide exposure to the Index consistent with its investment objective without regard to market conditions, trends or direction. The Fund's investment objective is a daily investment objective; that is, the Fund seeks to track the Index on a daily basis, not over longer periods. Accordingly, each day, the Fund will position its portfolio so that it can seek to track the Index. The direction and extent of the Index's movements each day will dictate the direction and extent of the Fund's portfolio rebalancing. For example, if the level of the Index falls on a given day, net assets of the Fund would fall. As a result, exposure to the Index, through futures positions held by the Fund, would need to be decreased. The opposite would be the case if the level of the Index rises on a given day.

The time and manner in which the Fund will rebalance its portfolio is defined by the Index methodology but may vary from the Index methodology depending upon market conditions and other circumstances including the potential impact of the rebalance on the price of the VIX Futures Contracts. The Sponsor will seek to minimize the market impact of rebalances across all exchange traded products based on VIX Futures Contracts ("VIX ETPs") that it sponsors ("Funds")²¹ on the price of VIX Futures Contracts by limiting the Funds' participation, on any given day, in VIX Futures Contracts to no more than 10% of the VIX Futures Contracts traded on Cboe Futures Exchange, Inc. ("CFE") during any "Rebalance Period," defined as any fifteen minute period of continuous market trading.²² To limit

are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

²¹ For purposes of the filing, the Exchange states that the Funds include the Fund and the 2x Long VIX Futures ETF ("Long Fund"), but may in the future include additional VIX ETPs sponsored by the Sponsor or its affiliates. *See Securities Exchange Act Release No. 93229 (Oct. 1, 2021) (SR-CboeBZX-2020-053) ("Long VIX Approval")*.

²² In the event that the Funds expect to hit the 10% threshold during the primary Rebalance Period from 3:45 p.m. to 4:00 p.m. ET, the Funds will extend their respective rebalances into additional

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ Rule 14.11(f)(4) applies to Trust Issued Receipts that invest in "Financial Instruments," defined in Rule 14.11(f)(4)(A)(iv) as any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars and floors; and swap agreements.

¹⁵ The Index is sponsored by Cboe Global Indexes ("Index sponsor"). The Index sponsor is not a registered broker-dealer, but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to the broker-dealer affiliate regarding access to information concerning the composition of and/or changes to the Index. In addition, the Index sponsor has implemented and will maintain procedures that are designed to prevent the use and dissemination of material, non-public information regarding the Index.

¹⁶ The Exchange states that the VIX is an index designed to measure the implied volatility of the S&P 500 over 30 days in the future. *See Amendment No. 1, supra* note 3, at 4, n.4. The VIX is calculated based on the prices of certain put and call options on the S&P 500. *See id.* The VIX is reflective of the premium paid by investors for certain options linked to the level of the S&P 500. *See id.*

¹⁷ The Exchange states that VIX Futures Contracts are measures of the market's expectation of the level of VIX at certain points in the future, and as such, will behave differently than current, or spot, VIX.

participation during periods of market illiquidity, the Sponsor, on any given day, may vary the manner and period over which all funds it sponsors are rebalanced, and as such, the manner and period over which the Fund is rebalanced. The Sponsor believes that the Fund will enter an Extended Rebalance Period most often during periods of extraordinary market conditions or illiquidity in VIX Futures Contracts. In the event that the Fund participates in an Extended Rebalance Period, the Fund represents that it will notify the Exchange and the Commission of such participation as soon as practicable, but no later than 9:00 a.m. ET on the trading day following the event.²³

III. Discussion and Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.²⁴ The Commission therefore approves the proposed rule change, as modified by Amendment Nos. 1 and 3.

The Commission received a number of comments letters addressing the proposed rule change's consistency with the Act, specifically focusing on (1) the potential for systemic risks; and (2) investor protection concerns, in particular the potential risks posed to retail investors. The Commission addresses each of these issues below. In addition, in approving the listing and trading of the Shares, the Commission also analyzes the proposal to ensure there is an appropriate regulatory framework to support the listing and trading of the Shares. Finally, the Commission addresses the procedural argument that the proposed rule change has been deemed approved and is currently in effect.

The record demonstrates the proposal is reasonably designed to mitigate the market impact and investor protection concerns articulated in the OIP and raised by commenters, and that the

Exchange has demonstrated that there is an appropriate regulatory framework to support the listing and trading of the Shares. Therefore, the Commission finds the proposal is consistent with the Act, in particular Section 6(b)(5).

A. Rebalance Design and Market Impact Considerations

Several of the commenters opposed to the proposal discuss the events of February 2018 as an example of the potential harm to retail investors and the potential systemic risk posed by volatility-linked exchange-traded products.²⁵ One commenter summarizes:

On February 5, 2018, after years of low market volatility, and accordingly a low VIX, the VIX doubled, a market event popularly known as "Volmageddon." One inverted VIX exchange-traded product ("ETP"), known as the VelocityShares Daily Inverse VIX Short-Term note ("XIV"), shrunk "from \$1.9 billion in assets to \$63 million in one session."²⁶

The commenter further states that the nature of VIX ETPs "contributed directly to the market volatility" because these types of products must rebalance in order to ensure the appropriate exposure to the index.²⁷ Two commenters describe the rebalance as a "feedback loop," because the issuer would have to purchase additional futures that would result in further declines for an inverse product.²⁸ According to one of the commenters, this feedback loop led to "all sorts of additional knock-effects for other market participants," including declines in major market indexes and investor losses in XIV.²⁹ A commenter states that each of the products proposed "involves the sort of rebalancing that exacerbated volatility during Volmageddon."³⁰

The Sponsor also acknowledges that "[p]ast and existing VIX ETPs rebalance or roll their futures contracts according to a methodology linked to the VIX

futures' settlement each day."³¹ Further, according to the Sponsor, daily settlement "has resulted in funds competing to execute their daily rebalance at a single point in time" resulting in "concentrated activity [that] erodes returns and may have contributed to at least one major market disruption."³² It describes previous attempts to reduce this concentration by reducing the leverage of other existing inverse and leveraged VIX ETPs as having "slowed the progression of market crowding," but concludes that these deleveraged products can still require "larger and larger rebalances at the same crowded settlement time" if they attract larger inflows.³³

The Sponsor further states that commenters arguing in favor of disapproval because of the failure of other VIX ETPs "miss a key point: lessons learned from the failures of previous products are at the very heart of the new methodology underlying [the proposed products]."³⁴ The Sponsor describes four ways the proposed products differ from previous and existing VIX ETPs: (1) The valuation is an average price over a longer time period instead of exclusively at the 4:00 p.m. ET settlement price; (2) a wider rebalancing period should distribute trading volume away from 4:00 p.m. ET, resulting in a more stable market; (3) the rebalance period may be extended to reduce market impact if required; and (4) the Sponsor has committed to a 10% participation cap for all VIX ETPs offered by the Sponsor.³⁵ The Sponsor states these differences should result in "an execution method that minimizes market impact and meaningfully lowers the chances of either [proposed product] experiencing a significant disruption"³⁶ and "less volatile products with minimal impacts to the underlying VIX futures and the broader market."³⁷

Other commenters write in favor of the Fund's rebalance design.³⁸ One commenter states that the "structural changes . . . incorporated into the

Rebalance Periods and the Trade at Settlement ("TAS") market. It is expected that this extension will provide the Funds with the flexibility to: begin rebalancing in an earlier period, end rebalancing in a later period, and execute contracts in TAS (each "an Extended Rebalance Period" and collectively "the Extended Rebalance Period") while remaining below the 10% cap during any 15-minute period of continuous market trading. See Amendment No. 1, *supra* note 3, at 11–12, n.10. The Funds will be allocated executions based on their percentage of notional transaction volume required. See *id.* at 12.

²³ See Amendment No. 3, *supra* note 3, at 5.

²⁴ In approving this proposed rule change, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁵ See letters from Americans for Financial Reform Education Fund, dated May 7, 2021 ("AFREF"); Dennis M. Kelleher, President and CEO; Stephen Hall, Legal Director and Securities Specialist; and Jason Grimes, Senior Counsel, Better Markets, Inc., dated May 7, 2021 ("Better Markets"); Tyler Gellasch, Executive Director, Healthy Markets Association, dated May 7, 2021 ("Healthy Markets"); and Robert Rutkowski, dated May 10, 2021 ("Rutkowski").

²⁶ Better Markets at 2.

²⁷ See Better Markets at 2.

²⁸ See Better Markets at 3 (citing Patrick Augustin, *et al.*, *Volmageddon and the Failure of Short Volatility Products* (Apr. 6, 2021, *Financial Analysts Journal*, Forthcoming)); and AFREF at 3.

²⁹ AFREF at 3–4.

³⁰ Better Markets at 3.

³¹ Letter from Barry I. Pershkov, Partner, Chapman and Cutler LLP, on behalf of the Sponsor, dated May 7, 2021 ("Volatility Shares 1") at 2.

³² Volatility Shares 1 at 2.

³³ See Volatility Shares 1 at 2.

³⁴ See letter from Stuart Barton, Chief Investment Officer, Sponsor, dated May 19, 2021 ("Volatility Shares 2") at 2.

³⁵ Volatility Shares 1 at 3.

³⁶ Volatility Shares 1 at 3.

³⁷ Volatility Shares 2 at 2.

³⁸ See letters from Soeren Bundgaard Broegger, Copenhagen Business School, dated January 1, 2021 ("Broegger"); Vance Harwood, President, Six Figure Investing, Advisory Board, Invest in Vol, dated January 4, 2021 ("Harwood"); Jim Carroll, dated January 7, 2021 ("Carroll"); and Peter Corrigan, dated January 7, 2021 ("Corrigan").

design of the [Fund] address critical shortcomings of prior short VIX products.”³⁹ One commenter states that, “although rebalancing flows from leveraged and inverse VIX products are usually absorbed in an orderly fashion . . . [there is] a potential benefit from distributing rebalancing flows more evenly across the trading day instead concentrating the flows around the time of the daily settlement.”⁴⁰ Another commenter asserts that the design of the product would “help insure the orderly rebalancing of this product, enhancing price discovery and liquidity of the VIX futures markets.”⁴¹ A commenter also states that the rebalance design and the participation cap dilute key information that encourages front running, liquidity withholding and other manipulative strategies, which substantially reduces the potential for fraudulent and manipulative acts and practices, and further states that the architecture of the Fund is a model for how all leveraged ETPs should be constructed.⁴²

In its proposal, as modified by Amendment Nos. 1 and 3, the Exchange states that the Sponsor’s proposed methodology for the Funds seeks to reduce the dependence of VIX ETPs on TAS by seeking to execute part of the Funds’ daily rebalance outside of TAS and believes that this approach will spread VIX futures trading activity over a longer period of time each day and should help to reduce market impact during periods of market turmoil or disruption.⁴³ In addition, the Exchange states that the Sponsor expects that allowing the Funds to participate in an Extended Rebalance Period will minimize the impact of the Funds’ rebalance on the price of VIX Futures Contracts, and particularly minimize any impact of large rebalances during periods of market illiquidity.⁴⁴ The Exchange further states that “the rebalancing mechanism to be used by the Funds is designed to reduce the Funds’ individual and collective impact on the volatility market and the associated potentially negative impact on the Funds.”⁴⁵

In its assessment of the proposal, the Commission considered the potential for market disruption during periods with large percentage increases in volatility and, because of the potential for large, sudden moves in VIX levels,

the potential for large spikes in rebalancing demand for VIX ETPs. As commenters note, the events of February 2018 occurred during a period when volatility had been relatively low and spiked, as the spot price of VIX more than doubled, and there was a large spike in the trading volume in VIX futures contracts at the end of day. A portion of the volume was attributable to the rebalancing demand of volatility-linked ETPs.

In the OIP, the Commission requested comment on the Fund’s operation during periods with large percentage increases in volatility and whether the Sponsor’s proposed limitation on the use of VIX Futures Contracts during its rebalance would sufficiently minimize the market impact of the Fund’s daily rebalance.⁴⁶ Following the OIP, the Exchange amended its proposal to state that the Sponsor will seek to minimize the market impact of rebalances across all Funds on the price of VIX Futures Contracts by limiting the Funds’ participation, on any given day, in VIX Futures Contracts to no more than ten percent of the VIX Futures Contracts traded on CFE during any Rebalance Period.⁴⁷

The Exchange’s proposal regarding the rebalancing methodology of the Fund serves as an appropriate limit on the Fund’s participation in the VIX futures market, and is reasonably designed to help mitigate the potential market impact on the Fund’s daily rebalance demand during periods when there are large percentage increases in volatility.⁴⁸ In discussing the events of “Volmageddon,” commenters describe several factors that may have contributed to the spike in futures prices: (1) Growing assets under management (“AUM”) for VIX ETPs, which in turn required more rebalancing; (2) a large percentage increase in volatility; and (3) a market where multiple funds were attempting

to rebalance simultaneously, and where the VIX futures TAS market was halted “limit up.”⁴⁹ The design of the rebalancing methodology helps to mitigate the first and third factors, even if there is a large percentage increase in volatility. Because the Funds’ must limit their participation in any Rebalance Period to 10%, the participation cap still serves as a limit on the Funds’ rebalancing demand during each Rebalance Period, regardless of AUM. Further, the Funds’ rebalance is spread over a longer time period and distributes trading away from a single point in time when other funds may be rebalancing,⁵⁰ and permits the Funds’ limited flexibility in order to reduce market impact, which may help reduce market crowding. In addition, the Commission observes that the VIX futures market has changed since the events of “Volmageddon:” (1) TAS has a wider permissible price range;⁵¹ and (2) VIX futures settle at 4:00 p.m. ET rather than 4:15 p.m. ET (*i.e.*, after the close of U.S. equity market trading).⁵²

In sum, the Commission considered the potential that VIX ETPs might have a destabilizing effect on markets during times of market stress. Based on the record, including commenters’ descriptions of the events of February 2018, the Commission concludes that the Exchange’s proposal is reasonably designed to help mitigate against the market impact concerns articulated in the OIP and by commenters opposed to the proposal. The rebalance design of the Funds may help distribute rebalancing volume. Further, the 10% participation cap strikes an appropriate balance between allowing the Funds to rebalance within a reasonably short period of time and managing the potential market impact of a large rebalance. Therefore, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,

⁴⁶ See OIP, *supra* note 3, 85 FR at 82538. As originally proposed, the Sponsor would have sought to minimize the market impact of Fund rebalances on the price of VIX Futures Contracts by limiting the Fund’s participation, on any given day, in VIX Futures Contracts to no more than one-quarter of the contracts traded on the CFE during any rebalance period (defined by the Index methodology as 3:45 p.m. to 4:00 p.m. ET.). See Notice, *supra* note 3, 85 FR 59836 at 59839.

⁴⁷ See Amendment No. 1, *supra* note 3, at 11.

⁴⁸ A commenter states that the Commission should not view individual product proposals in isolation. See Better Markets at 6. Although the Commission’s findings in this order are based on the specific proposed rule change filed with the Commission, including how the proposed rule operates under the current market conditions discussed in this order, the Commission recognizes that, over time, market conditions in VIX ETP markets, and the related VIX futures market, may change.

⁴⁹ See letter from Stuart Barton, Head of Investments, Sponsor, dated January 6, 2021, at n. 1.

⁵⁰ For example, two existing leveraged VIX ETPs target a 4 p.m. ET benchmark. See Securities Exchange Act Release No. 90691 (Dec. 16, 2020), 85 FR 83643 (Dec. 22, 2020) (SR—CboeBZX—2020—093).

⁵¹ See Cboe Product Update, “Price Parameter Change for TAS Transactions in VX Futures,” 2018, available at: https://cdn.cboe.com/resources/product_update/2018/VX-Trade-at-Settlement-VXT-Price-Parameter-Change.pdf.

⁵² See Cboe Futures Exchange, LLC Rule Certification, Submission Number CFE—2020—028 (September 23, 2020), available at: https://cdn.cboe.com/resources/regulation/rule_filings/pending/2020/20-028-Daily-Settlement-Determination-Time.pdf#:~:text=The%20Daily%20Settlement%20Time%20for%20VX%20futures%20is,for%20VX%20futures%20is%203%3A00%20p.m.%20Chicago%20time.

³⁹ Carroll.

⁴⁰ See Broegger.

⁴¹ See Corrigan.

⁴² See Harwood, at 1.

⁴³ See Amendment No. 1, *supra* note 3, at 12–13.

⁴⁴ See *id.*

⁴⁵ Letter from Kyle Murray, Vice President, Associate General Counsel, Cboe Global Markets, dated May 7, 2021 (“BZX Letter”) at 2.

including the protection of investors and the public interest.

B. Investor Protection

Commenters also raise concerns about the risks and complexity of leveraged and inverse VIX ETPs and their suitability for retail investors. One of the commenters asserts that: (1) Recent market events and the public record with the VIX raise significant questions about the investor-protection risks posed by VIX-related investment products; (2) such questions must be adequately addressed by filings to list and trade more VIX-related products; and (3) the Exchange has not explained how explain how its proposed listing and trading of the Shares would be consistent with the Act, including the protection of investors.⁵³ Another commenter states that the absence of new sales practices protections for leveraged investment products “leaves investors with extremely inadequate protections in this space.”⁵⁴ According to the commenter, shares of leveraged exchange-traded funds are unsuitable for retail investors because they provide markedly different returns—and generally significantly underperform—their underlying indices over the long-term.⁵⁵ That commenter also asserts that it would be inconsistent with the protection of investors to facilitate gambling-like market practices by approving additional products that enable leveraged bets on synthetic indexes.⁵⁶ More specifically, the commenter states that the Shares would not directly support economic activity and, in the commenter’s view, the assertion that any hedging achieved through the Shares would lead to a net gain in real capital formation is not supported.⁵⁷ Commenters also state that the products are inconsistent with the Act because there are “inherent dangers” for leveraged exchange-traded products that make them unsuitable for retail investors.⁵⁸ Finally, one commenter states that the Approval Order does not adequately address the risks to investors and to retail investors in particular.⁵⁹

Several commenters urge the Commission to approve the Fund and assert that it would meet an unmet need in the market for certain investors.⁶⁰ Commenters state that certain investors replicate the inverse VIX strategy by shorting other VIX-related ETPs, which, according to commenters, may result in greater risks and higher costs for such investors.⁶¹ One commenter asserts that “the Fund provides a more predictable investment that has lower complexity and a better-defined risk profile.”⁶²

In response to commenters opposed to the proposal, the Sponsor states that commenters’ concerns related to leveraged and inverse exchange-traded products, and in particular the concern that such products underperform their benchmarks over time, have been raised previously. It states that such products are not designed to perform over long periods of time, and that courts have “affirmed the adequacy of the disclosure contained in the registration statement of these products.”⁶³ In addition, the Exchange states that the proposed products would provide “investors with new tools to implement investment strategies to which they might not otherwise have access.”⁶⁴ The Sponsor also cites the Commission’s recent amendments to Rule 6c–11 of the Investment Company Act of 1940, which would include certain leveraged and inverse exchange-traded funds within the scope of Rule 6c–11, as well as the Commission’s approvals of leveraged and inverse exchange-traded products that are not registered investment companies.⁶⁵ The Sponsor asserts that this demonstrates that questions related to leveraged and inverse products have been therefore “asked and answered.”⁶⁶

The Commission acknowledges commenters’ concerns, but believes this proposed rule change is consistent with the protection of investors. Commenters

assert that the Exchange has not met its burden to demonstrate the proposal is consistent with the protection of investors because leveraged and inverse exchange-traded products, in particular those linked to volatility, are complex and risky, and underperform their benchmarks over time. The Commission has recognized that certain complex products, such as inverse or leveraged exchange-traded products, “which may be useful for some sophisticated trading strategies, are highly complex financial instruments and are typically designed to achieve their stated objectives on a daily basis.”⁶⁷ However, there are existing rules and standards of conduct applicable to other complex products that would apply to listing and trading of the Shares. The best interest standard of conduct for broker-dealers required under Regulation Best Interest and the fiduciary obligations of investment advisers discussed in the Fiduciary Interpretation thereto apply to transactions in all exchange-traded products where the transaction is recommended by a broker-dealer or pursuant to the advice of an investment adviser.⁶⁸ In addition, the Financial Industry Regulatory Authority (“FINRA”) has implemented increased sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged and inverse leveraged securities (which include the Shares), and has provided specific guidance regarding sales practice obligations for volatility-linked exchange-traded products.⁶⁹ Exchange members that carry customer accounts will be required to follow the FINRA guidance set forth in these notices. The Exchange also has rules relating to suitability, in particular BZX Rule 3.7.⁷⁰

⁶⁷ Regulation Best Interest Adopting Release, Exchange Act Rel. No. 86031 (Jun. 5, 2019), 84 FR 33318 (Jul. 12, 2019), at 33376.

⁶⁸ See Investment Company Act Rel. No. 34084, (Nov. 2, 2020), 85 FR 83217 (Dec. 21, 2020), at 83217–18 (discussing the best interest standard of conduct for broker-dealers and the fiduciary obligations of investment advisers in the context of all exchange-traded products).

⁶⁹ See FINRA Regulatory Notices 09–31 (Jun. 2009), 09–53 (Aug. 2009), 09–65 (Nov. 2009), 12–03 (Jan. 2012), and 17–32 (Oct. 2017).

⁷⁰ In particular, Rule 3.7 imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers and Interpretation and Policy .01 of BZX Rule 3.7 imposes a duty of due diligence on Exchange members to learn the essential facts relating to every customer prior to trading the Shares, and specifically provides that “[n]o Member shall recommend to a customer a transaction in any such product unless the Member has a reasonable basis for believing at the time of making the recommendation that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks of the recommended

Continued

⁵³ See Healthy Markets at 6.

⁵⁴ AFREF at 1–2.

⁵⁵ See AFREF at 2. Another commenter asserts that certain investors purchasing shares of the Long Fund may “be surprised to see that their losses would be amplified by a factor of 2 during periods of low volatility” and, in the view of this commenter, both products raise investor protection concerns because they are “complex and risky.” See Better Markets at 4–5.

⁵⁶ See AFREF at 2.

⁵⁷ See AFREF at 3.

⁵⁸ See Rutkowski, Healthy Markets at 2–3.

⁵⁹ See Better Markets at 4–5.

⁶⁰ See letters from Jay Soloff, Lead Options Analyst, Investors Alley, dated December 30, 2020 (“Soloff”); Russell Rhoads, Head of Research and Consulting, EQDerivatives, dated January 14, 2021 (“Rhoads”); Invest in Vol, dated January 6, 2021 (“Invest in Vol”); Carroll; Harwood at 2.

⁶¹ See Carroll (stating investors may be “better served” with direct exposure rather than short sales); Harwood; Invest in Vol, at 2; and Soloff. See also Rhoads (stating the absence of a short VIX ETP excludes certain investors from opportunities afforded to hedge fund investors).

⁶² Harwood. However, a commenter on the Long Fund questions the profitability and utility of a 2x long product. See Long VIX Approval, *supra* note 21, at n.50, n. 53 and accompanying text.

⁶³ Volatility Shares 2 at 1–2.

⁶⁴ BZX Letter at 2. The Exchange states that the Funds would provide greater short and long exposure than ETPs currently trading on U.S. exchanges. See *id.*

⁶⁵ See Volatility Shares 2 at 1–2.

⁶⁶ Volatility Shares 2 at 1–2.

Therefore, the Commission finds that this proposal is consistent with the Act, in particular the protection of investors and the public interest.⁷¹

C. Other Considerations

In addition, the Commission analyzed other aspects of the Exchange's proposal and finds, as explained below, that the proposal is consistent with the Act because it is designed to prevent fraudulent and manipulative acts and practices and protect investors and the public interest. The Exchange has demonstrated there is an appropriate regulatory framework to support listing and trading of the Shares, including trading rules, surveillance, and listing standards.

The proposal is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading in the Shares when a reasonable degree of certain pricing transparency cannot be assured. Specifically, the Exchange will obtain a representation from the Sponsor of the Shares that the NAV will be calculated daily and that the NAV and the Fund's holdings will be made available to all market participants at the same time. On each Business Day,⁷² before commencement of trading in Shares during Regular Trading Hours,⁷³ the Fund will disclose on its website the holdings that will form the basis for the Fund's calculation of NAV at the end of the Business Day. This website disclosure of the portfolio composition of the Fund will occur at the same time as the disclosure by the Fund of the portfolio composition to authorized participants, so that all market participants will be provided portfolio composition information at the same time, and the same portfolio information will be provided on the public website as in electronic files provided to authorized participants. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association. As required by BZX Rule 14.11(f)(4), an updated Intraday

transaction and is financially able to bear the risks of the recommended position."

⁷¹ Although the Commission finds the proposal is consistent with the Exchange Act, the Commission is not expressing a view about whether the Shares are appropriate or suitable for all investors.

⁷² A "Business Day" means any day other than a day when any of BZX, Cboe, CFE, or other exchange material to the valuation or operation of the Fund, or the calculation of the VIX, options contracts underlying the VIX, VIX Futures Contracts or the Index is closed for regular trading.

⁷³ As defined in BZX Rule 1.5(w), the term "Regular Trading Hours" means the time between 9:30 a.m. and 4:00 p.m. ET.

Indicative Value ("IIV") will be calculated and widely disseminated by one or more major market data vendors every 15 seconds throughout Regular Trading Hours. The IIV will be published on the Exchange's website and will be available through on-line information services such as Bloomberg and Reuters. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The Fund's website will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. In addition, the level of the Index will be published at least every 15 seconds in real time from 9:30 a.m. to 4:00 p.m. ET and at the close of trading on each Business Day by Bloomberg and Reuters.

Quotation and last-sale information regarding VIX Futures Contracts and VIX Options Contracts will be available from the exchanges on which such instruments are traded. Quotation and last-sale information relating to VIX Options Contracts will also be available via the Options Price Reporting Authority. Quotation and last-sale information for VIX Swap Agreements will be available from nationally recognized data services providers, such as Reuters and Bloomberg, through subscription agreements or from a broker-dealer who makes markets in such instruments. Pricing information regarding Cash Equivalents in which the Fund may invest is generally available through nationally recognized data services providers, such as Reuters and Bloomberg, through subscription agreements. The closing prices and settlement prices of the Index Components (*i.e.*, the first- and second-month VIX Futures Contracts) will be readily available from the websites of CFE (<http://www.cfe.cboe.com>), automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. The CFE also provides delayed futures information on current and past trading sessions and market news free of charge on its website. Complete real-time data for component VIX Futures Contracts underlying the Index, including the specific contract specifications of Index Components (*i.e.*, first-month and second-month VIX Futures Contracts), is available by subscription from Reuters and Bloomberg.

The Exchange's rules regarding trading halts further help to ensure the maintenance of fair and orderly markets for the Shares, which is consistent with

the protection of investors and the public interest. Trading in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the daily disclosed portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, the Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18 (Trading Halts Due to Extraordinary Market Volatility). BZX Rule 14.11(f)(4)(c)(ii) enumerates additional circumstances under which the Exchange will consider the suspension of trading in and will commence delisting proceedings for the Shares.

The Exchange's proposal is designed to safeguard material non-public information relating to the Fund's portfolio. Specifically, as the Exchange states, the Sponsor is not a broker-dealer or affiliated with a broker-dealer. In the event that (a) the Sponsor becomes a broker-dealer or newly affiliated with a broker-dealer, or (b) any new sponsor is a broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the portfolio. Moreover, trading of the Shares will be subject to BZX Rule 14.11(f)(4)(D), which sets forth certain restrictions on Exchange members acting as registered Market Makers⁷⁴ in Trust Issued Receipts to facilitate surveillance. In addition, the Exchange has a general policy prohibiting the distribution of material, non-public information by its employees.

Furthermore, the Exchange or FINRA, on behalf of the Exchange, or both, will communicate and may obtain information regarding trading in the Shares and the underlying listed instruments, including listed derivatives held by the Fund, with the Intermarket Surveillance Group ("ISG"), other markets or entities who are members or affiliates of the ISG, or with which the

⁷⁴ As defined in BZX Rule 1.5(l), the term "Market Maker" means an Exchange member that acts as a Market Maker pursuant to Chapter XI of the BZX Rules.

Exchange has entered into a comprehensive surveillance sharing agreement. The trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, and these procedures are adequate to properly monitor Exchange trading of the Shares during all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. In addition, all of the VIX Futures Contracts and VIX Options Contracts held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Moreover, the trading of the Shares on the Exchange will be subject to the Exchange's and other rules listed below. Specifically:

(1) The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities;

(2) The Shares will conform to the initial and continued listing criteria under BZX Rule 14.11(f);

(3) Pursuant to BZX Rule 14.11(a), all statements and representations made in the filing regarding the Index composition, description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of the Index, reference assets, and IIV, or the applicability of Exchange listing rules specified in the filing shall constitute continued listing requirements for the Shares. The issuer will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

(4) The Exchange has the appropriate rules to facilitate transactions in the Shares during all trading sessions;

(5) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares;⁷⁵

⁷⁵ The Exchange states that the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (c)

(6) FINRA has implemented increased sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged and inverse leveraged securities (which include the Shares) and options on such securities, as described in FINRA Regulatory Notices 09–31 (June 2009), 09–53 (August 2009), and 09–65 (November 2009). Exchange members that carry customer accounts will be required to follow the FINRA guidance set forth in these notices;

(7) For initial and continued listing, the Fund and the Trust must be in compliance with Rule 10A–3 under the Act;⁷⁶ and

(8) A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

D. Procedural Considerations

The Sponsor also asserts that the proposed rule change has been deemed approved pursuant to Exchange Act Section 19(b)(2)(D)(ii).⁷⁷ The Commission disagrees with the Sponsor's assertions that: (1) Because the Approval Order is stayed, "the Commission did not effectively approve or disapprove [the Proposal] by the 240th day" and therefore the proposal has been deemed approved;⁷⁸ and (2) the Commission's discretionary review of the order by delegated authority

Interpretation and Policy .01 of BZX Rule 3.7 which imposes a duty of due diligence on its members to learn the essential facts relating to every customer prior to trading the Shares, and specifically provides that "[n]o Member shall recommend to a customer a transaction in any such product unless the Member has a reasonable basis for believing at the time of making the recommendation that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks of the recommended transaction and is financially able to bear the risks of the recommended position;" (d) how information regarding the IIV and the Fund's holdings is disseminated; (e) the risks involved in trading the Shares during the Pre-Opening and After Hours Trading Sessions (as such terms are defined in BZX Rules) when an updated IIV will not be calculated or publicly disseminated; (f) the requirement that Exchange members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (g) trading information.

⁷⁶ 17 CFR 240.10A–3.

⁷⁷ See Volatility Shares 1 at 4. Section 19(b) of the Exchange Act requires the Commission to "issue an order" approving or disapproving a proposed rule change within, at most, 240 days of the proposed rule change's filing. See 15 U.S.C. 78s(b)(2)(B)(ii). If the Commission fails to issue an order within that period, the proposed rule change is deemed to have been approved. See 15 U.S.C. 78s(b)(2)(D).

⁷⁸ See Volatility Shares 1 at 4. The Sponsor asserts that, because the Commission did not act on SR–CboeBZX–2020–070 before May 21, 2021, the proposal has been deemed approved.

conflicts with the purpose and language of the statute.⁷⁹

The Commission complied with the requirements of the statute. Section 19(b)(2)(D) requires only that the Commission "issue an order" approving or disapproving the proposed rule change within 240 days. The Approval Order was issued within that period.

Although orders issued by delegated authority are issued by Commission staff, they are issued with the full authority of the Commission and are signed by the Secretary's office on behalf of the Commission. Section 4A of the Exchange Act authorizes the Commission to delegate certain functions—including approval or disapproval of proposed rule changes under Section 19—to a "division of the Commission."⁸⁰ And the Commission's Rules of Practice make clear that "an action made pursuant to delegated authority shall have immediate effect and be deemed the action of the Commission."⁸¹

IV. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.

It is therefore ordered, pursuant to Rule 431 of the Commission's Rules of Practice, that the earlier action taken by delegated authority, Securities Exchange

⁷⁹ See Volatility Shares 1 at 2.

⁸⁰ 15 U.S.C. 78d–1(a).

⁸¹ Commission Rule of Practice 431(e), 17 CFR 201.431(e). See also, e.g., Rule of Practice 430(c), 17 CFR 201.430(c) (referring to "a final order entered pursuant to [delegated authority]"); Rule of Practice 431(f), 17 CFR 201.431(f) (giving an order by delegated authority operative effect, even when review has been sought, until a person receives actual notice that it was stayed, modified, or reversed on review). Moreover, as the Commission has previously explained, Congress was aware of the Commission's ability to delegate authority to approve SRO rule filings when the time restrictions in Exchange Act Section 19(b)(2)(D) were enacted. And to construe Section 19(b)(2), as the Sponsor does, to require Commission review of an order by delegated authority to be completed within 240 days "would undermine both the specific deadlines set forth in the statute and the Commission's ability to delegate functions. Nor is such a construction necessary to fulfill Congress's purpose in enacting the deadlines to "streamline" the rule filing process. With rare exception, rule filings are decided, by delegated authority or otherwise, within 240 days. See Securities Exchange Act Release Nos. 88493 (Mar. 27, 2020), 85 FR 18617 (Apr. 2, 2020) (Order Affirming Action by Delegated Authority and Disapproving Proposed Rule Changes Related to Connectivity and Port Fee in the Matter BOX Exchange LLC) at 18626; and 82727 (Feb. 15, 2018), 83 FR 7793 (Feb. 22, 2017) (Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, Regarding the Acquisition of CHX Holdings, Inc. by North America Casin Holdings, Inc.) at 7799.

Act Release No. 91264 (March 5, 2021), 86 FR 13939 (March 11, 2021), is set aside and, pursuant to Section 19(b)(2) of the Act, the proposed rule change (SR-CboeBZX-2020-070), as modified by Amendment Nos. 1 and 3, hereby is approved.

By the Commission.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21877 Filed 10-6-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93235; File No. SR-ICC-2021-020]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the Stress Testing Framework and the Indirect Participant Risk Monitoring and Review Policy

October 1, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 27, 2021, ICE Clear Credit LLC (“ICC”) filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to amend the Stress Testing Framework and to adopt and formalize the Indirect Participant Risk Monitoring and Review Policy (“Indirect Participant Risk Policy”). These revisions do not require any changes to the ICC Clearing Rules (the “Rules”).

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may

be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to amend the Stress Testing Framework and to adopt and formalize the Indirect Participant Risk Policy. The proposed amendments to the Stress Testing Framework include clarifications on the stress testing practices of ICC and reference the Indirect Participant Risk Policy. The proposed Indirect Participant Risk Policy describes the monitoring and review of risk arising from and relating to indirect participants, which are the underlying clients of ICC’s Clearing Participants (“CPs”). ICC believes that such revisions will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. ICC proposes to move forward with implementation of such changes following Commission approval of the proposed rule change. The proposed revisions are described in detail as follows.

I. Stress Testing Framework

The revisions to the Stress Testing Framework are intended to clarify ICC’s stress testing practices and include minor clean-up changes. The proposed changes abbreviate various terms throughout the document, starting in Section 2. Regarding the stress test methodology in Section 3, ICC would define financial resources as available funds from the Initial Margin requirements and Guaranty Fund contributions related to the selected portfolios in a footnote, and make minor conforming terminology changes in the text regarding the analyzed Initial Margin requirements. A proposed appendix with details on ICC’s stress test methodology would be referenced throughout the amended document, specifically in Sections 3, 5, and 13. Proposed footnotes in Subsection 5.1 contain formulas that provide further definition regarding certain historically observed extreme but plausible market scenarios. The proposed amendments to Section 12 specify that client stress testing is executed daily (rather than “at least monthly”) and reference the Indirect Participant Risk Policy for further details. In Section 14, ICC proposes a grammatical update to make “meeting” plural and to memorialize

that the Stress Testing Framework is subject to review by the Risk Committee and review and approval by the Board at least annually. ICC proposes to include the Indirect Participant Risk Policy as a reference in Section 15.

ICC proposes new Section 16 as an appendix, which is intended to provide more detail and clarity on ICC’s stress test methodology and would not change the methodology. The proposed appendix defines key terms and sets out underlying formulas and equations used for stress testing. Key terms include Stress Testing Profit/Losses, which represent the CP portfolio hypothetical response to the considered stress testing scenarios. Moreover, the appendix explains the determination of the order of defaulting CP Affiliate Groups (“AGs”) in order to establish if the available financial resources are sufficient to cover hypothetical losses associated with the two greatest CP AG uncollateralized stress losses and discusses the consideration given to wrong way risk exposure. Finally, the appendix details how ICC determines if the available financial resources are sufficient to cover the hypothetical losses associated with the two greatest CP AG uncollateralized losses under the extreme but plausible scenarios.

II. Indirect Participant Risk Policy

The risk management program at ICC includes various elements designed to ensure the adequate identification, monitoring and management of risks arising from and relating to indirect participants. The proposed Indirect Participant Risk Policy memorializes such practices and analyses and sets forth the associated governance arrangements. The document is divided into seven sections, which are detailed below.

Section 1 introduces the purpose of the document and defines key terms. Indirect participants are defined as the underlying clients of ICC’s CPs. ICC’s CPs with clients are referred to as Futures Commission Merchants/Broker Dealers (“FCMs/BDs”) throughout the document. Indirect Participants can pose risk to CPs and indirectly to ICC due to the presence of Large Traders. A Large Trader includes a client of a CP that exhibits large risk exposure in its portfolio that transpires through concentrated position(s), significant level of collateralization and large uncollateralized losses under extreme but plausible market stress scenarios.

Sections 2 through 4 describe and memorialize the identification, monitoring, and risk management practices related to indirect participants and the presence of Large Traders.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Section 2 introduces a report that enables ICC to determine the presence of potential Large Traders and assess the level of risk that they may pose to the CP and/or ICC. Client risk exposure across all FCMs/BDs and corresponding indirect participants are summarized in this report, which allows the ICC Risk Department to monitor and identify the FCMs/BDs with the largest indirect participants. Section 3 details a report summarizing ICC's indirect participants with risk profiles prone to adverse risk distribution, due to their size, across all FCMs/BDs. The criteria for the selection of indirect participants in this report is set out in the Indirect Participant Risk Policy. Further, Section 3 describes a complementary report, which would indicate the probability of an indirect participant adversely distributing its risk across multiple FCMs/BDs and provide guidance on additional indirect participants to be included for reporting. Individual client portfolio level stress testing is executed and presented through another report discussed in Section 4. The selection of indirect participants and FCMs/BDs for this analysis as well as relevant assumptions are also explained in Section 4. Moreover, each section details the frequency of execution or review of the report by the ICC Risk Department and the frequency of review by the ICC Risk Committee.

Section 5 memorializes governance procedures associated with the performance and review of the aforementioned analyses. The Indirect Participant Risk Policy specifies the group or individual involved in the execution, interpretation, review, and reporting of the analyses as well as the frequency. Section 5 also sets out the actions to be taken if the ICC Risk Department and the ICC Risk Committee deem the risk arising from indirect participants to be significant. In Sections 6 and 7, ICC includes references and a revision history.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act³ and the regulations thereunder applicable to it, including the applicable standards under Rule 17Ad-22.⁴ In particular, Section 17A(b)(3)(F) of the Act⁵ requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by

ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest. The proposed changes strengthen the Stress Testing Framework by providing more detail on the methodology through defined terms and references to relevant documentation and formulas or equations, memorializing the review and approval process, and making other clarification and clean-up changes to ensure that it remains up-to-date and transparent. The proposed Indirect Participant Policy describes and memorializes the practices and analyses governing the identification, monitoring, and review of risk arising from and relating to indirect participants and sets forth the associated governance arrangements. ICC believes that the proposed rule change will ensure that responsible parties carry out their assigned duties effectively with respect to stress testing and managing risk from indirect participants, thereby promoting the prompt and accurate clearing and settlement of the contracts cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.⁶

The amendments would also satisfy relevant requirements of Rule 17Ad-22.⁷ Rule 17Ad-22(e)(2)(i) and (v)⁸ requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. The proposed changes strengthen the governance procedures in the Stress Testing Framework by memorializing the review and approval process by relevant groups at least annually. The proposed Indirect Participant Risk Policy details governance procedures associated with the performance and review of analyses related to indirect participants. Specifically, this document specifies the group or individual involved in the execution, interpretation, review, and reporting of the analyses as well as the frequency. As such, in ICC's view, the proposed rule change continues to ensure that ICC maintains policies and procedures that are reasonably designed to provide for clear and transparent governance

arrangements and specify clear and direct lines of responsibility, consistent with Rule 17Ad-22(e)(2)(i) and (v).⁹

Rule 17Ad-22(e)(3)(i)¹⁰ requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes risk management policies, procedures, and systems designed to identify, measure, monitor, and manage the range of risks that arise in or are borne by the covered clearing agency, that are subject to review on a specified periodic basis and approved by the Board annually. ICC maintains a sound risk management framework that identifies, measures, monitors, and manages the range of risks that it faces. The Stress Testing Framework is a key aspect of ICC's risk management approach, and the proposed amendments would memorialize that the document is reviewed by the ICC Risk Committee and reviewed and approved by the ICC Board at least annually. As such, the amendments would satisfy the requirements of Rule 17Ad-22(e)(3)(i).¹¹

Rule 17Ad-22(e)(4)(ii)¹² requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions. The proposed amendments enhance ICC's ability to manage its financial resources by providing further clarity and transparency on the stress test methodology and on the procedures and analyses related to managing risk from indirect participants. The proposed rule change would thus enhance the implementation of such policies and procedures by ensuring that responsible parties effectively carry out their associated duties, thereby

⁹ *Id.*

¹⁰ 17 CFR 240.17Ad-22(e)(3)(i).

¹¹ *Id.*

¹² 17 CFR 240.17Ad-22(e)(4)(ii).

³ 15 U.S.C. 78q-1.

⁴ 17 CFR 240.17Ad-22.

⁵ 15 U.S.C. 78q-1(b)(3)(F).

⁶ *Id.*

⁷ 17 CFR 240.17Ad-22.

⁸ 17 CFR 240.17Ad-22(e)(2)(i) and (v).

supporting ICC's ability to maintain its financial resources and withstand the pressures of defaults, consistent with the requirements of Rule 17Ad-22(e)(4)(ii).¹³

Rule 17Ad-22(e)(4)(vi)¹⁴ requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements, including by conducting stress testing of its total financial resources once each day using standard predetermined parameters and assumptions; conducting a comprehensive analysis on at least a monthly basis of the existing stress testing scenarios, models, and underlying parameters and assumptions; and reporting the results of its analyses to appropriate decision makers at ICC. The proposed rule change continues to ensure that ICC's policies and procedures, including the Stress Testing Framework and Indirect Participant Risk Policy, provide a clear framework for ICC to conduct stress testing and analysis and report the results to appropriate decision makers at ICC, in compliance with this requirement. The Indirect Participant Risk Policy would memorialize governance procedures associated with the performance and review of analyses related to indirect participants, including the frequency of execution or review and reporting to the ICC Risk Committee. As such, ICC believes the proposed rule change is consistent with the requirements of Rule 17Ad-22(e)(4)(vi).

Rule 17Ad-22(e)(19)¹⁵ requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to identify, monitor, and manage the material risks to the covered clearing agency arising from arrangements in which firms that are indirect participants in the covered clearing agency rely on the services provided by direct participants to access the covered clearing agency's payment, clearing, or settlement facilities. As described above, the proposed Indirect Participant Risk Policy documents ICC's processes and procedures related to indirect participants, including how ICC

identifies, analyzes, escalates, and reports on indirect participants. The document ensures responsibility and accountability by detailing the group or individual involved in the execution, interpretation, and review of reports, the frequency of execution and review, and the actions to be taken if the risk arising from indirect participants is deemed significant. Accordingly, ICC believes that the proposed rule change promotes its ability to identify, monitor, and manage the material risks to it related to indirect participants and is thus consistent with the requirements of Rule 17Ad-22(e)(19).¹⁶

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition. The proposed changes to amend the Stress Testing Framework and to adopt and formalize the Indirect Participant Risk Policy will apply uniformly across all market participants. Therefore, ICC does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

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-ICC-2021-020 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-ICC-2021-020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at <https://www.theice.com/clear-credit/regulation>. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-ICC-2021-020 and should be submitted on or before October 28, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21865 Filed 10-6-21; 8:45 am]

BILLING CODE 8011-01-P

¹³ *Id.*

¹⁴ 17 CFR 240.17Ad-22(e)(4)(vi).

¹⁵ 17 CFR 240.17Ad-22(e)(19).

¹⁶ *Id.*

¹⁷ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93234; File No. SR–FICC–2021–007]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change To Remove the Early Unwind Intraday Charge, Change the Treatment of Short-Term Treasuries, and Make Other Changes

October 1, 2021.

On August 13, 2021, Fixed Income Clearing Corporation (“FICC”) 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 proposed rule change SR–FICC–2021–007 (the “Proposed Rule Change”) to amend (1) the FICC Government Securities Division (“GSD”) Rulebook (“Rules”)³ in order to remove the Early Unwind Intraday Charge (“EUIIC”), (2) the GSD Methodology Document—GSD Initial Market Risk Margin Model (“QRM Methodology Document”) to change the treatment of U.S. Treasury (“Treasury”) securities with remaining time-to-maturities equal to or less than a year (“Short-Term Treasuries”), and (3) the Rules and the QRM Methodology Document to make certain technical changes, as described more fully below. The Proposed Rule Change was published for public comment in the *Federal Register* on August 31, 2021,⁴ and the Commission received no comment letters regarding the changes proposed therein. For the reasons discussed below, the Commission is approving the Proposed Rule Change.

I. Description of the Proposed Rule Change

A. Elimination of the EUIIC for the GCF Repo Service

The GCF Repo service allows members of FICC’s Government Securities Division to trade general collateral finance repos (“GCF Repos”)⁵ throughout the day without requiring

intraday, trade-for-trade settlement on a delivery-versus-payment basis. A key tool that FICC uses to manage its respective credit exposures to its members is the daily collection of margin from each member. The aggregated amount of all members’ margin constitutes the Clearing Fund, which FICC would access should a defaulted member’s own margin be insufficient to satisfy losses to FICC caused by the liquidation of that member’s portfolio. The EUIIC was adopted as a component of margin in 2014 and is generally determined based on the risk posed by underlying collateral pertaining to GCF Repo positions in FICC’s 12 p.m. intraday margin call. The purpose of the EUIIC is to address the under-margined conditions that can occur in two situations in the GCF Repo service involving the substitution of securities with cash.⁶ The first situation may occur when, on an intraday basis, a GCF Repo Member substitutes cash for the securities that had been used as collateral for a GCF Repo position the prior day. The second situation may occur when the GCF Clearing Agent Bank unwound the cash lending side of a GCF Repo Transaction that occurred on an interbank basis⁷ at approximately 7:30 a.m.⁸ FICC represents that both of these situations had the potential to result in higher cash balances in the underlying collateral of GCF Repo positions at 12:00 p.m. when FICC is calculating the intraday margin associated with GCF Repo positions.⁹ These situations could cause an under-margined condition because there is no VaR Charge associated with cash collateral,¹⁰ and the GCF Repo Member

would likely replace the cash with securities (which would be subject to the VaR Charge) by end of day.

FICC represents that it can address the first situation described above by applying the Intraday Supplemental Fund Deposit, as updated in 2018,¹¹ instead of the EUIIC.¹² The current EUIIC is only applied based on a Netting Member’s 12:00 p.m. GCF Repo positions, as the lesser of (i) the net reduction in the VaR Charge attributable to either cash substitutions, or (ii) the prior end of day VaR Charge minus the intraday VaR Charge.¹³ On the other hand, FICC receives hourly intraday GCF Repo lockup files from 8:00 a.m. to 3:00 p.m. from The Bank of New York Mellon.¹⁴ These hourly intraday GCF Repo lockup files provide FICC with information with respect to the GCF Repo Members’ positions throughout the day that FICC can use to calculate an intraday VaR Charge. As such, throughout the day, FICC can use the information in these files to assess the exposure that arises from collateral substitution (in addition to any other position changes) and can charge an Intraday Supplemental Fund Deposit amount to the GCF Repo Member, if necessary, to address this exposure.

Regarding the second situation described above, the situation no longer exists because interbank services were suspended in 2016, and accordingly, the unwind of the cash lending side of a GCF Repo Transaction that occurred on an interbank basis does not take place.¹⁵

B. Treatment of Short-Term Treasuries

The confidentially filed QRM Methodology Document, which describes the current GSD margin methodology, does not reflect any special treatment for determining the margin for transactions in Short-Term Treasuries. Short-Term Treasuries are margined as part of the entire portfolio using the sensitivity VaR Charge methodology, and a haircut-based methodology is used as a backup for Short-Term Treasuries where sensitivity analytics data is not available. Specifically, Short-Term Treasuries that do not have sensitivity analytics data are subject to a single haircut rate calibrated to the volatility of the

009). There is no VaR Charge associated with cash collateral because there is no need for liquidation.

¹¹ See Securities Exchange Act Release No. 83362 (June 1, 2018), 83 FR 26514 (June 7, 2018) (SR–FICC–2018–001) and 83223 (May 1, 2018), 83 FR 23020 (May 17, 2018) (FICC–2018–801).

¹² Notice, *supra* note 4, at 48771.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See Securities Exchange Act Release No. 78206 (June 30, 2016), 81 FR 44388 (July 7, 2016) (SR–FICC–2016–002).

⁶ Securities Exchange Act Release Nos. 73389 (October 17, 2014), 79 FR 63456 (October 23, 2014) (SR–FICC–2014–01) and 73388 (October 17, 2014), 79 FR 63458 (October 23, 2014) (SR–FICC–2014–801).

⁷ At the time of the EUIIC approval, the GCF Repo Service was operating on both an “interbank” and “intraday” basis. “Interbank” means that the two GCF Repo Members which have been matched in a GCF Repo transaction each clear at a different clearing bank. “Intraday” means that the two GCF Repo Members which have been matched in a GCF Repo transaction clear at the same clearing bank. The GCF Repo Service now operates on an intraday basis only because the interbank service of the GCF Repo service is no longer available. See Securities Exchange Act Release No. 78206 (June 30, 2016), 81 FR 44388 (July 7, 2016) (SR–FICC–2016–002).

⁸ All times herein are Eastern Time.

⁹ Notice, *supra* note 4, at 48771.

¹⁰ The value-at-risk (“VaR”) Charge is designed to capture the risks related to the movement of market prices associated with the securities in a member’s portfolio, and calculate the potential losses on a portfolio over a three-day period of risk assumed necessary to liquidate the portfolio. See Securities Exchange Act Release No. 90182 (October 14, 2020), 85 FR 66630 (October 20, 2020) (SR–FICC–2020–

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ Capitalized terms used herein and not defined shall have the meaning assigned to such terms in the Rules, available at <http://www.dtcc.com/legal/rules-and-procedures.aspx>.

⁴ Securities Exchange Act Release No. 92756 (August 25, 2021), 86 FR 48770 (August 31, 2021) (SR–FICC–2021–007) (“Notice”).

⁵ A GCF Repo is one in which the lender of funds is willing to accept any of a class of U.S. Treasuries, U.S. government agency securities, and certain mortgage-backed securities as collateral for the repurchase obligation. This is in contrast to a specific collateral repo.

Bloomberg/Barclays Index of Treasury securities with remaining time-to-maturities equal to or less than a year.

FICC represents that one concern with the current approach is related to the potentially large impact that market events can have on the yields of Short-Term Treasuries. Under the current approach, the VaR Charge calculated for portfolios with a high concentration of Short-Term Treasuries may not adequately cover the potentially large impact on the “short-end” of the Treasury yield curve.¹⁶ FICC represents that another concern with the current approach is that it may not adequately address the volatility of certain portfolios of Short-Term Treasuries if the composition of those portfolios differs greatly from the composition of the Bloomberg/Barclays Index of Treasury securities described above. Using one haircut rate based on the volatility of the Bloomberg/Barclays index may not adequately cover the risk of securities with longer duration maturities in the equal to or less than one-year.¹⁷

In order to address the concerns above, FICC proposes to use a haircut methodology to margin all Short-Term Treasuries and not just for the Short-Term Treasuries without sensitivity analytics data. In addition, FICC proposes to use two different haircut rates depending on the time to maturity of the Short-Term Treasuries. The first rate would apply to Treasury securities with remaining time to maturity equal to or less than six months with a haircut floor set at 12.5 basis points. The second rate would apply to Treasury securities with remaining time to maturity greater than six months but equal to or less than one year with a haircut floor set at 25 basis points. The haircut charges would be applied to the absolute value of the net market value of the Treasury securities in the respective rates, and the correlation offset would not be applied.

FICC examined the backtesting results of the current approach, as applied at a product level, for Short-Term Treasuries.¹⁸ The results show that the current approach does not meet FICC’s 99% confidence level standard.¹⁹ FICC’s backtesting results for the period between January and December 2020 showed that the Proposed Rule Change

would improve the backtesting results from approximately 94.9% to 99.4%.²⁰

C. Technical Changes

FICC proposes to make conforming technical changes to renumber the paragraphs in Section 1b of Rule 4. FICC also proposes to make technical changes to the QRM Methodology Document. Specifically, FICC proposes to make clarifying and grammatical changes to a sentence that describes the indices in a haircut used for short TIPS bonds.

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act²¹ directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization. After careful consideration, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations applicable to FICC.²² In particular, the Commission finds that the Proposed Rule Change is consistent with Section 17A(b)(3)(F)²³ of the Act and Rules 17Ad–22(e)(4)(i)²⁴ and 17Ad–22(e)(6)(i)²⁵ thereunder.

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F)²⁶ of the Act requires, in part, that the rules of a clearing agency, such as FICC, be designed to, among other things, promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.

As described in Section I.A. above, the proposed change to eliminate the EUIC is designed to provide more accurate coverage by avoiding potential under-margining due to the two situations described involving cash substitution. As stated above, the EUIC was established in 2014 to reduce this risk of potential under-margining. However, in 2018, FICC amended its methodology for determining the VaR

Charge and clarified the nature of the Intraday Supplemental Fund Deposit to more effectively address market volatility. As described above, the EUIC is applied based on data produced once per day while the Intraday Supplemental Fund Deposit is based on hourly information. Accordingly, the Intraday Supplemental Fund Deposit can more accurately calculate margin the exposure presented. Furthermore, the second situation involving interbank transactions no longer exists because inter bank services were suspended in 2016.

As described in Section I.B. above, the proposed changes to the QRM Methodology Document are designed to mitigate the vulnerabilities of the current GSD margin methodology when it is applied to portfolios with a high concentration of Short-Term Treasuries. As stated above, the current GSD Margin methodology does not reflect any special treatment for determining the margin for Short-Term Treasuries. Currently, Short-Term Treasuries are margined as part of the entire portfolio using the sensitivity VaR Charge methodology, and a haircut-based methodology is used as a backup where sensitivity analytics data is not available. Pursuant to the Proposed Rule Change, a haircut methodology would be used to margin all Short-Term Treasuries and two different haircuts with floors would be used depending on the time to maturity of the Short-Term Treasuries. The proposed changes would help FICC to calculate and collect adequate margin for Short-Term Treasuries from members. Moreover, the backtesting results show that the Proposed Rule Change would help FICC achieve its backtesting standards, which is a 99 percent coverage target with 3-days of margin period of risk.

As described in Section I.C. above, the proposed technical changes to the QRM Methodology Document would enhance the clarity of the document for FICC. As the QRM Methodology Document is used by FICC’s risk management personnel regarding the calculation of margin requirements, the proposed changes would help ensure that FICC’s personnel understand and apply the calculation of the GSD margin methodology.

Taken together, the Commission believes that the Proposed Rule Change would allow FICC to more accurately calculate each member’s margin. This enhancement, in turn, would help FICC to produce margin levels more commensurate with the risks associated with its members’ portfolios, and more effectively cover its credit exposure to its members. FICC’s collection of margin

²⁰ *Id.*

²¹ 15 U.S.C. 78s(b)(2)(C).

²² The Commission’s findings are based on its review of the Proposed Rule Change, including its analysis of the backtesting results, which are summarized in Section I.B. above. See *supra* note 18 and accompanying text.

²³ 15 U.S.C. 78q–1(b)(3)(F).

²⁴ 17 CFR 240.17Ad–22(e)(4)(i).

²⁵ 17 CFR 240.17Ad–22(e)(6)(i).

²⁶ 15 U.S.C. 78q–1(b)(3)(F).

¹⁶ Notice, *supra* note 4, at 48772.

¹⁷ *Id.*

¹⁸ FICC filed the backtesting results as a confidential Exhibit 3 to the Proposed Rule Change pursuant to 17 CFR 240.24b–2. Backtesting is an ex-post comparison of actual outcomes with expected outcomes derived from the use of margin methodology.

¹⁹ Notice, *supra* note 4, at 48772.

amount in a manner that fully manages FICC's applicable credit exposures should help ensure that, in the event of a member default, FICC's operations would not be disrupted and non-defaulting members would not be exposed to losses that they cannot anticipate or control. Accordingly, the Commission finds that NSCC's Proposed Rule Change is designed to help promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.²⁷ Moreover, FICC's collection of margin amounts that better limit FICC's credit exposure to members would help ensure that FICC maintains adequate funds necessary to manage the risks associated with performing its clearance and settlement functions, which could, in turn, help reduce the amount of credit losses that would be distributed to non-defaulting members in the event of a default. Accordingly, the Commission finds that FICC's Proposed Rule Change is designed to help promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds that are in FICC's custody or control. Therefore, the Commission believes that the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act.²⁸

B. Consistency With Rule 17Ad-22(e)(4)(i)

Rule 17Ad-22(e)(4)(i) under the Act²⁹ requires a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those exposures arising from its payment, clearing, and settlement processes by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.

The proposed change to eliminate the EUIC is designed to more accurately address the potential under-margining situations described above. The EUIC is charged once a day, while FICC may charge an Intraday Supplemental Fund Deposit amount, if necessary, throughout the day, based on the hourly information that FICC receives regarding GCF Repo Members' positions. As such, because FICC can continuously assess its exposure and charge additional margin throughout the day with the Intraday Supplemental Fund Deposit rather than at one point in time, the

proposed changes would help FICC better measure and monitor its credit exposures to members.

The proposed changes to the QRM Methodology Document are designed to allow FICC to use the haircut methodology to determine the margin for all Short-Term Treasuries and not just for the Short-Term Treasuries without sensitivity analytics data, as is the current case. In addition, FICC would differentiate Short-Term Treasuries based on the time to maturity, and apply two haircuts. This proposed approach would address the deficiencies with the current approach when it is applied to portfolios with a high concentration of Short-Term Treasuries as described above and thereby better enable FICC to limit its credit exposures to members.

Therefore, for the reasons discussed above, the Commission believes that the Proposed Rule Change is consistent with the requirements of Rule 17Ad-22(e)(4)(i) under the Act.³⁰

C. Consistency With Rule 17Ad-22(e)(6)(i)

Rule 17Ad-22(e)(6)(i) under the Act³¹ requires a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.

The proposed change to eliminate the EUIC and thus relying on Intraday Supplemental Fund Deposit to calculate and collect margins is designed to cover FICC's credit exposures to its members. As described above, Intraday Supplemental Fund Deposit would better enable FICC to consider and produce margin levels commensurate with the risk and particular attributes of a GCF Repo Member's portfolio and is able to be more precisely tailored to the risks presented by a particular portfolio because it allows for more frequent consideration of the appropriate charge, as opposed to at one point during the day under the EUIC.

The proposed changes to the QRM Methodology Document are designed to cover FICC's credit exposures to its members, especially those members who have a high concentration of Short-Term Treasuries in their portfolios

because, as described above, this proposed approach would address two vulnerabilities associated with the current approach when it is applied to portfolios with a high concentration of Short-Term Treasuries. By providing targeted margin methodologies for Short-Term Treasuries and addressing two vulnerabilities, the proposed changes would enhance NSCC's ability to cover its credit exposures to its members and produce margin levels commensurate with the risks and particular attributes of Short-Term Treasuries.

Therefore, for the reasons discussed above, the Commission believes that the Proposed Rule Change is consistent with the requirements of Rule 17Ad-22(e)(6)(i) under the Act.³²

III. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act³³ and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act³⁴ that Proposed Rule Change SR-FICC-2021-007, be, and hereby is, *approved*.³⁵

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21863 Filed 10-6-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93231; File No. SR-NYSECHX-2021-14]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Rule 7.12

October 1, 2021.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the

³² *Id.*

³³ 15 U.S.C. 78q-1.

³⁴ 15 U.S.C. 78s(b)(2).

³⁵ In approving the Proposed Rule Change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

³⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

²⁷ *Id.*

²⁸ *Id.*

²⁹ 17 CFR 240.17Ad-22(e)(4)(i).

³⁰ *Id.*

³¹ 17 CFR 240.17Ad-22(e)(6)(i).

“Act”)² and Rule 19b-4 thereunder,³ notice is hereby given that, on September 30, 2021, the NYSE Chicago, Inc. (“NYSE Chicago” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II, below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rule 7.12 to the close of business on March 18, 2022. 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 extend the pilot related to the market-wide circuit breaker in Rule 7.12 to the close of business on March 18, 2022.

Background

The Market-Wide Circuit Breaker (“MWC”) rules, including the Exchange’s Rule 7.12, provide an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when cash equities securities experience extreme market-wide declines. The MWC rules are designed to slow the effects of extreme price declines through coordinated

trading halts across both cash equity and equity options securities markets.

The cash equities rules governing MWCs were first adopted in 1988 and, in 2012, all U.S. cash equity exchanges and FINRA amended their cash equities uniform rules on a pilot basis (the “Pilot Rules,” *i.e.*, Rule 7.12 (a)–(d)).⁴ The Pilot Rules currently provide for trading halts in all cash equity securities during a severe market decline as measured by a single-day decline in the S&P 500 Index (“SPX”).⁵ Under the Pilot Rules, a market-wide trading halt will be triggered if SPX declines in price by specified percentages from the prior day’s closing price of that index. The triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. and before 3:25 p.m. would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. would not halt market-wide trading. (Level 1 and Level 2 halts may occur only once a day.) A market decline that triggers a Level 3 halt at any time during the trading day would halt market-wide trading for the remainder of the trading day.

The Commission approved the Pilot Rules, the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the “LULD Plan”),⁶ including any extensions to the pilot period for the LULD Plan.⁷ In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.⁸ In light of the proposal to make the LULD Plan permanent, the

Exchange amended Article 20, Rule 2 to untie the pilot’s effectiveness from that of the LULD Plan and to extend the pilot’s effectiveness to the close of business on October 18, 2019.⁹ After the Commission approved the Exchange’s proposal to transition to trading on Pillar,¹⁰ the Exchange subsequently amended the corresponding Pillar rule—Rule 7.12—to extend the pilot’s effectiveness for an additional year to the close of business on October 18, 2020,¹¹ and later, on October 18, 2021.¹²

The Exchange now proposes to amend Rule 7.12 to extend the pilot to the close of business on March 18, 2022. This filing does not propose any substantive or additional changes to Rule 7.12.

The MWC Task Force and the March 2020 MWC Events

In late 2019, Commission staff requested the formation of a MWC Task Force (“Task Force”) to evaluate the operation and design of the MWC mechanism. The Task Force included representatives from the SROs, the Commission, CME, the Commodity Futures Trading Commission (“CFTC”), and the securities industry and conducted several organizational meetings in December 2019 and January 2020.

In Spring 2020, the MWC mechanism proved itself to be an effective tool for protecting markets through turbulent times. In March 2020, at the outset of the worldwide COVID-19 pandemic, U.S. equities markets experienced four MWC Level 1 halts, on March 9, 12, 16, and 18, 2020. In each instance, the markets halted as intended upon a 7% drop in the S&P 500 Index, and resumed as intended 15 minutes later.

In response to these events, in the Spring and Summer of 2020, the Task Force held ten meetings that were attended by Commission staff, with the goal of performing an expedited review of the March 2020 halts and identifying any areas where the MWC mechanism had not worked properly. Given the risk of unintended consequences, the Task Force did not recommend changes that were not rooted in a noted deficiency. The Task Force recommended creating a process for a backup reference price in

⁴ See Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR-BATS-2011-038; SR-BYX-2011-025; SR-BX-2011-068; SR-CBOE-2011-087; SR-C2-2011-024; SR-CHX-2011-30; SR-EDGA-2011-31; SR-EDGX-2011-30; SR-FINRA-2011-054; SR-ISE-2011-61; SR-NASDAQ-2011-131; SR-NSX-2011-11; SR-NYSE-2011-48; SR-NYSEAmex-2011-73; SR-NYSEArca-2011-68; SR-Phlx-2011-129) (“Pilot Rules Approval Order”).

⁵ The rules of the equity options exchanges similarly provide for a halt in trading if the cash equity exchanges invoke a MWC Halt. See, e.g., NYSE Arca Rule 6.65-O(d)(4).

⁶ See Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

⁷ See Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR-CHX-2011-30) (Approval Order); and 68777 (January 31, 2013), 78 FR 8673 (February 6, 2013) (SR-CHX-2013) (Notice of Filing of Immediate Effectiveness of Proposed Rule Change Delaying the Operative Date of a Rule Change to CHX Article 20, Rule 2).

⁸ See Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

⁹ See Securities Exchange Act Release No. 85565 (April 9, 2019), 84 FR 15239 (April 15, 2019) (SR-NYSECHX-2019-05).

¹⁰ See Securities Exchange Act Release No. 87264 (October 9, 2019), 84 FR 55345 (October 16, 2019) (SR-NYSECHX-2019-08).

¹¹ See Securities Exchange Act Release No. 87027 (September 19, 2019), 84 FR 50484 (September 25, 2019) (SR-NYSECHX-2019-09).

¹² See Securities Exchange Act Release No. 90140 (October 8, 2020), 85 FR 65888 (October 16, 2020) (SR-NYSECHX-2020-30).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

the event that SPX were to become unavailable, and enhancing functional MWCB testing. The Task Force also asked CME to consider modifying its rules to enter into a limit-down state in the futures pre-market after a 7% decline instead of 5%. CME made the requested change, which became effective on October 12, 2020.¹³

The MWCB Working Group's Study

On September 17, 2020, the Director of the Commission's Division of Trading and Markets asked the SROs to conduct a more complete study of the design and operation of the Pilot Rules and the LULD Plan during the period of volatility in the Spring of 2020.

In response to the request, the SROs created a MWCB "Working Group" composed of SRO representatives and industry advisers that included members of the advisory committees to both the LULD Plan and the NMS Plans governing the collection, consolidation, and dissemination of last-sale transaction reports and quotations in NMS Stocks. The Working Group met regularly from September 2020 through March 2021 to consider the Commission's request, review data, and compile its study. The Working Group's efforts in this respect incorporated and built on the work of an MWCB Task Force.

The Working Group submitted its study to the Commission on March 31, 2021 (the "Study").¹⁴ In addition to a timeline of the MWCB events in March 2020, the Study includes a summary of the analysis and recommendations of the MWCB Task Force; an evaluation of the operation of the Pilot Rules during the March 2020 events; an evaluation of the design of the current MWCB system; and the Working Group's conclusions and recommendations.

In the Study, the Working Group concluded: (1) The MWCB mechanism set out in the Pilot Rules worked as intended during the March 2020 events; (2) the MWCB halts triggered in March 2020 appear to have had the intended effect of calming volatility in the market, without causing harm; (3) the design of the MWCB mechanism with respect to reference value (SPX), trigger levels (7%/13%/20%), and halt times (15 minutes) is appropriate; (4) the

change implemented in Amendment 10 to the Plan to Address Extraordinary Market Volatility (the "Limit Up/Limit Down Plan" or "LULD Plan") did not likely have any negative impact on MWCB functionality; and (5) no changes should be made to the mechanism to prevent the market from halting shortly after the opening of regular trading hours at 9:30 a.m.

In light of the foregoing conclusions, the Working Group also made several recommendations, including that the Pilot Rules should be permanent without any changes.¹⁵

Proposal To Extend the Operation of the Pilot Rules Pending the Commission's Consideration of the New York Stock Exchange LLC's Filing To Make the Pilot Rules Permanent

On July 16, 2021, the Exchange's affiliate, the New York Stock Exchange ("NYSE"), proposed a rule change to make the Pilot Rules permanent, consistent with the Working Group's recommendations.¹⁶ On August 27, 2021, the Commission extended its time to consider the proposed rule change to October 20, 2021.¹⁷ The Exchange now proposes to extend the expiration date of the Pilot Rules to the end of business on March 18, 2022.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁸ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁹ 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. The market-wide circuit breaker mechanism under Rule 7.12 is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional five months would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission reviews the Exchange's

proposed rule change to make the Pilot Rules permanent.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from Pilot Rules should continue on a pilot basis because they will promote fair and orderly markets and 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 because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act²⁰ and Rule 19b-4(f)(6) thereunder.²¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the

¹³ See https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20-392_1.pdf; https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20-392_2.pdf.

¹⁴ See Report of the Market-Wide Circuit Breaker ("MWCB") Working Group Regarding the March 2020 MWCB Events, submitted March 31, 2021 (the "Study"), available at https://www.nyse.com/publicdocs/nyse/markets/nyse/Report_of_the_Market-Wide_Circuit_Breaker_Working_Group.pdf.

¹⁵ See *id.* at 46.

¹⁶ See Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (July 22, 2021) (SR-NYSE-2021-40).

¹⁷ See Securities Exchange Act Release No. 92785A (August 27, 2021), 86 FR 50202 (September 7, 2021) (SR-NYSE-2021-40).

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

²⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

²¹ 17 CFR 240.19b-4(f)(6).

proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)²² normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²³ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Extending the pilot Rules' effectiveness to the close of business on March 18, 2022 will extend the protections provided by the Pilot Rules, which would otherwise expire in less than 30 days. Waiver of the operative delay would therefore permit uninterrupted continuation of the MWCB pilot while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.²⁴

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)²⁵ 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-NYSECHX-2021-14 on the subject line.

Paper Comments

- *Send paper comments in triplicate to:* Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSECHX-2021-14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSECHX-2021-14 and should be submitted on or before October 28, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-21870 Filed 10-6-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93237; File No. SR-Phlx-2021-56]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing of Proposed Rule Change To Amend Options 4A, Section 12 Regarding the Closing Volume Weighted Average Price ("Closing VWAP") for Listing and Trading of Options on the Nasdaq-100® Volatility Index

October 1, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 23, 2021, Nasdaq PHLX LLC ("Phlx" 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 its rule regarding options on the Nasdaq-100® Volatility Index within Options 4A, Section 12, Terms of Index Options Contracts.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/phlx/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.

²² 17 CFR 240.19b-4(f)(6).

²³ 17 CFR 240.19b-4(f)(6)(iii).

²⁴ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁵ 15 U.S.C. 78s(b)(2)(B).

²⁶ 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

The Exchange proposes to amend the Nasdaq-100[®] Volatility Index ("Volatility Index") within Options 4A, Section 12, Terms of Index Options Contracts. Specifically, the Exchange proposes to amend the calculation of the final settlement price for VOLQ options, the Closing Volume Weighted Average Price or "Closing VWAP," in the event any of the thirty-two underlying Nasdaq-100[®] index ("NDX") component options do not have a trade/quote during the 300 second period of time (the "Closing Settlement Period").

Background

The final settlement price for the Volatility Index is calculated on Wednesday of each week commencing at 9:32:010 a.m. on the expiration day, and continuing each second for the next 300 seconds (New York time).³ The settlement value for the Volatility Index is the Closing VWAP that is determined by reference to the prices and sizes of executed orders⁴ or quotes in the thirty-two underlying NDX component options⁵ on Phlx, Nasdaq ISE, LLC ("ISE") and Nasdaq GEMX, LLC ("GEMX")⁶ calculated at the opening of trading on the expiration date (usually a Wednesday). At the end of individual one-second time observations during the Closing Settlement Period, which commences at 9:32:010 on the expiration day (or 2.00.01 minutes after the open of trading in the event trading does not commence at 9:30:000 a.m. ET),⁷ and continues each second for the

next 300 seconds, the number of contracts resulting from orders⁸ and quotes executed on Phlx, ISE and GEMX at each price during the observation period is multiplied by that price to yield a Reference Number. All Reference Numbers are then summed, and that sum is then divided by the total number of contracts traded during the observation period [Sum of (contracts traded at a price × price) ÷ total contracts traded] to calculate a Volume Weighted Average Price for that observation period (a "One Second VWAP") for that component option. If no transactions occur on Phlx, ISE and/or GEMX, during any one-second observation period, the NBBO midpoint at the end of the one second observation period will be considered the One Second VWAP for that observation period for purposes of this settlement methodology. Specifically, the Closing VWAP would seek the best bid and best offer (which may consist of a quote or an order) from among the listing markets (Phlx, ISE and GEMX markets). Each One Second VWAP for each component option is then used to calculate the Volatility Index, resulting in the calculation of 300 sequential Volatility Index values. Finally, all 300 Volatility Index values are arithmetically averaged (*i.e.*, the sum of 300 Volatility Index calculations is divided by 300) and the resulting figure is rounded to the nearest .01 to arrive at the settlement value disseminated under the ticker symbol "VOLS."⁹

Proposal

The Exchange proposes to amend the Closing VWAP to provide for an alternative calculation of the Closing Settlement Period if during any one second of the Closing Settlement Period any of the thirty-two NDX option series does not have a trade/quote. The alternative observation window would be part of the proposed new calculation of the Closing Settlement Period. The Exchange would add the alternate observation window to the existing calculation of the Closing VWAP.

First, the Exchange proposes if, during any one second of the observation period, any of the thirty-two NDX option series used for Closing VWAP does not have a trade/quote, the index calculator would look back and

use the most recent published quote¹⁰ midpoint during that day for the One Second VWAP for the option component that does not have a trade/quote. If there is no One Second VWAP to utilize for any of the thirty-two NDX option series during the Closing Settlement Period, then the index calculator will consider that Closing Settlement Period invalid and will be unable to determine a Closing VWAP at that time.

Second, in the event the Closing Settlement Period is invalid and a Closing VWAP cannot be determined, the index calculator will then roll the Closing Settlement Period forward by one second and determine if there is a One Second VWAP for each of the thirty-two NDX option series for all 300 consecutive seconds of the new Closing Settlement Period. If there is a One Second VWAP for all of the thirty-two NDX option series for all 300 consecutive seconds, a Closing VWAP will be calculated. If a One Second VWAP is not present for all of the thirty-two NDX option series during the new observation period, the index calculator will again roll the Closing Settlement Period forward by one second. The index calculator would continue to roll the Closing Settlement Period forward by one second until such time as it is able to capture a One Second VWAP for each of the thirty-two NDX option series for all 300 consecutive seconds. At that time, a Closing VWAP will be calculated.

The proposal seeks to create an automated, non-discretionary process by which the Exchange would determine the Closing VWAP in the event any of the thirty-two underlying NDX component options do not have a trade/quote during the Closing Settlement Period. By creating an automated process, the Closing VWAP would be calculated consistently with the proposed rule. The Exchange does not anticipate utilizing the alternative Closing VWAP calculation on a regular basis. In fact, a review of 43 expiration dates¹¹ from January 2018 through July 2021 revealed invalid values for only 2 expiration dates.¹² On both of the expiration dates, the Exchange would have obtained a One Second VWAP for

³ The exercise settlement amount would be equal to the difference between the final settlement price and the exercise price of the option, multiplied by \$100. Exercise would result in the delivery of cash on the business day following expiration.

⁴ The Exchange proposes to add rule text within Options 4A, Section 12(b)(6)(D) to further describe what is meant by executed orders. Today, the rule text states, "Executed orders shall include simple orders and complex orders however, individual leg executions of a complex order will only be included if the executed price of the leg is at or within the NBBO." The proposed change will be described in the proposal section.

⁵ Dependent upon movement in the Nasdaq-100 Index, all of the Closing Settlement Period index (VOLS) thirty-two underlying NDX component options can change every second making live market final settlement replication unfeasible over 300 seconds.

⁶ The Volatility Index's component NDX options are listed on Phlx as well as on the Exchange's affiliates, ISE and GEMX.

⁷ If the Exchange is unable to publish a settlement value by 12:00 p.m. (New York Time) due to a trading halt, the Exchange will determine and publish a value on its website. In the event of a trading halt, the Exchange will commence the

calculation of the settlement window beginning 2.00.01 minutes after the re-opening of trading. See Options 4A, Section 12(b)(6)(D)(II).

⁸ Executed orders include simple orders and complex orders, however, individual leg executions of a complex order will only be included if the executed price of the leg is at or within the NBBO.

⁹ See Options 4A, Section 12(b)(6)(D)(II), "Terms of Option Contracts."

¹⁰ Only quotes would be considered, not trades. The Exchange believes that quotes are more reflective of true market value since the index calculator would look back.

¹¹ The Exchange reviewed the 9,660 NBBO inputs for the VOLS computation from 9:32.01 for the five minute Closing Settlement Period for each expiration date.

¹² The expiration dates were March 18, 2020 and June 17, 2020. The Exchange notes that the options industry experience unprecedented volumes in 2020.

the component by looking forward because the look back did not contain a quote for the component that was missing a One Second VWAP.

In the event of a trading halt in one or more options, excluding a trading halt in all Nasdaq-100 index options, prior to the completion of the Closing Settlement Period, the Exchange would continue to look back for a One Second VWAP prior to looking forward. The Exchange believes that it is important to maintain a consistent process for obtaining missing values for the Closing VWAP. As noted above, the Exchange does not believe the alternative method would be utilized with any frequency, rather it should be utilized infrequently. In the event a trading halt caused Market Makers to not submit a Valid Width Quote in certain components during the Opening Process,¹³ the alternative methodology would look forward to obtain a value. Also, the Exchange would utilize a quote from the Opening Process only in the event an options series was able to open. If the Opening Process did not complete for an options series, there would be no value to obtain for a component during a look back.¹⁴

Today, Options 4A, Section 12(b)(6)(D)(II) provides, "If the Exchange is unable to publish a settlement value by 12:00 p.m. (New York time) due to a trading halt, the Exchange will commence the calculation of the settlement window beginning 2.00.01 minutes after the re-opening of trading and publish that value on its website."¹⁵ The Exchange proposes to replace this rule text with language which provides, "In the event of a trading halt in all Nasdaq-100 index options, the Exchange would commence the calculation of the settlement window beginning 2:00:01¹⁶ minutes after the re-opening of trading and publish that value on its website. In this scenario, the Exchange would not look back prior to the trading halt." The Exchange's proposal amends the current sentence to eliminate the 12:00 p.m. timeframe which does not consider all possible scenarios. A re-opening could occur anytime during the trading day. Further, specifically indicating a trading halt of the Nasdaq-100 index options in the rule text is more precise as the impact to the Nasdaq-100 index options

is a direct concern for VOLQ. The proposed language more directly expands upon the manner in which the Closing VWAP will be handled in the event of a trading halt.

While the Exchange believes that the Volatility Index Closing VWAP has exceedingly high hurdles for potential manipulation, the proposed amendments would provide for a Closing Settlement Period, which has published liquidity for all of the thirty-two NDX option series used for the Closing VWAP. This proposed amendment would permit the index calculator to seek a One Second VWAP by first looking back for the most recent published quote midpoint for that option that had no trade/quote. In the event the Closing Settlement Period is invalid and a Closing VWAP cannot be determined, the index calculator will then continuously roll the Closing Settlement Period forward by one second until there is a One Second VWAP for all of the thirty-two NDX option series for all 300 consecutive seconds. This proposed change is designed to ensure that all thirty-two NDX components have a One Second VWAP for the calculation of the Closing VWAP.

For example, assume that during the first 59 seconds of the observation period, beginning at 9:32:01 a.m., all thirty-two NDX option components had a One Second VWAP. During the 60th second, the required NDX component June 18, 2021 14,100 call does not have a trade and has a market of \$0.00 bid @ \$0.00 offer. The index calculator would look back to the most recent quote, which occurred at 09:32:57 a.m. and would use that quote in the calculation to determine a One Second VWAP for the 60th second (09:33:00 a.m.). However, if during the look back, no quote has occurred since market open, the observation period up to and including the 60th second would be considered invalid and the new observation period would begin with the next second. In that case, the new observation period would begin at 09:33:01 a.m. and would continue for 300 seconds as long as there is a One Second VWAP which can be determined for all 32 NDX component options.

During the scenario above, if during the 58th, 59th, and 60th second, the required NDX component June 18, 2021 14,100 call does not have a trade and has a market of \$0.00 bid @ \$0.00 offer, then the index calculator would look back to the most recent quote which occurred at 09:32:57 a.m. and would use that value in the calculation to

determine the One Second VWAP for the 58th, 59th, and 60th second.

The Exchange believes that its proposal would ensure that the Closing VWAP is calculated using options with sufficient liquidity for each of the thirty-two NDX components by seeking component values that are represented by trades and/or quotes. The Exchange believes that initially looking back for the most recent published quote midpoint for that option will ensure an efficient price for that option component.¹⁷ If the Exchange is unable to obtain a One Second VWAP for any of the thirty-two NDX option series during the Closing Settlement Period, the Exchange will invalidate the Closing Settlement Period and move on to calculate the Closing VWAP utilizing a forward rolling observation period of one second.

The Exchange believes rolling the Closing Settlement Period forward by one second to obtain a One Second VWAP for each of the thirty-two NDX option series for all 300 consecutive seconds of the new observation period would ensure that the Closing VWAP is calculated using sufficient liquidity for each of the thirty-two NDX components by seeking trades and/or quotes in a new observation period. Utilizing a one second period of time to acquire a new observation window would allow the Exchange to utilize an observation window closest in time to the original window. Also, moving forward in increments of one second, as necessary, would serve to methodically move through the trading day for a potential observation window that would satisfy the Exchange's liquidity requirements. This method would continue to assess the entire field of NDX options prices each second to select specific listed NDX options to obtain the prices of synthetic precisely at-the-money options. As with the initial Closing Settlement Period, since the market is subject to constant change during three hundred individual one-second time periods for which listed options will be included in Closing VWAP, market participants cannot predict which option components will be included because that would entail predicting where the NDX price level (a function of predicting the price of all one-hundred component stocks) will be at the end of each of the three hundred individual one-second time periods. In addition, the Exchange notes that the look back period would likely not be subject to manipulation as the historical information would only be utilized in

¹⁷ The Exchange's calculation is dependent upon values for the 32 component options.

¹³ The Phlx Opening Process is described within Options 3, Section 8.

¹⁴ The Closing Settlement Period occurs within seconds of the completion of the Opening Process.

¹⁵ See Phlx Options 4A, Section 12(b)(6)(D).

¹⁶ The time when the Exchange will commence the calculation of the settlement window was corrected from 2.00.01 minutes to 2:00:01 minutes. The calculation begins on the second.

the event that liquidity was unavailable in the original observation window, which contains options components, which cannot be predicted.

The Exchange reiterates that it is unlikely that the Volatility Index Closing VWAP could be manipulated. In particular, because the thirty-two component Volatility Index option inputs¹⁸ are reviewed each second as the market changes to determine the at-the-money strikes (meaning that Volatility Index components could change 300 times during the Closing Settlement Period), market participants could manipulate the Closing VWAP only if they could replicate such value by guessing exact market moves over an extended period of 300 million microseconds. Because the likelihood of replication is extremely low, the Exchange believes that it is unlikely the Closing VWAP could be manipulated.

Nonetheless, the Exchange, in its normal course of surveillance, will monitor for any potential manipulation of the Volatility Index settlement value according to the Exchange's current procedures. Additionally, the Exchange would monitor the integrity of the Volatility Index by analyzing trades, quotations, and orders that affect any of the 300 calculated reference prices for any of the NDX option series used for the Closing VWAP for potential manipulation on the Exchange.

Finally, the Exchange proposes to amend the term "executed orders" at Options 4A, Section 12, (b)(6)(D)(II) which currently provides, "Executed orders shall include simple orders and complex orders however, individual leg executions of a complex order will only be included if the executed price of the leg is at or within the NBBO." The Exchange proposes to instead provide, "Executed orders shall include simple orders and complex orders (excluding out-of-sequence and late trades), however, individual leg executions of a complex order will only be included if the executed price of the leg is at or within the NBBO." The Exchange desires to exclude out-of-sequence and late trades to avoid potential stale data in the Closing VWAP calculation.

Implementation

The Exchange proposes to issue an Options Trader Alert announcing the day it will launch options on Nasdaq-100 Volatility Index. The Exchange initially indicated that it would launch

¹⁸ The Exchange notes that due to the number of proposed components, the mathematical formula would prevent the Volatility Index from exceeding 12.5% in any single component and 43.5% for the top 5 components.

these options by Q3 2021.¹⁹ At this time, the Exchange proposes to launch VOLQ options on or before March 31, 2022.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁰ in general, and furthers the objectives of Section 6(b)(5) of the Act,²¹ in particular, in that it will permit options trading in the Volatility Index pursuant to rules designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade by amending its Volatility Index to create additional alternative observations periods to arrive at a Closing VWAP in the event that any of the thirty-two NDX option series used for Closing VWAP do not have a One Second VWAP during the five minute Closing Settlement Period. Phlx's proposal to amend the Closing VWAP by proposing alternate observations periods would ensure a Closing Settlement Period which has published liquidity for all of the thirty-two NDX option series used for Closing VWAP. The Exchange notes that this alternate methodology may be utilized where there is no liquidity in any of the thirty-two NDX option series used for Closing VWAP. This may be caused by an Exchange system issue, market maker issue, or some news or halt in an underlying.

The proposal would promote just and equitable principles of trade by creating an automated, non-discretionary process by which the Exchange would determine the Closing VWAP in the event any of the thirty-two underlying NDX component options do not have a trade/quote during the Closing Settlement Period. The Closing VWAP would be calculated consistently. The Exchange anticipates the alternative Closing VWAP calculation would be utilized infrequently. In the event of a trading halt in one or more options, excluding a trading halt in all Nasdaq-100 index options, prior to the completion of the Closing Settlement Period, the Exchange's proposal to look back for a One Second VWAP, prior to looking forward, is consistent with the Act because the Exchange's process would be consistent for obtaining missing values for the Closing VWAP.

¹⁹ See Securities Exchange Act Release No. 91781 (May 5, 2021), 86 FR 25918 (May 11, 2021) (SR-PHLX-2020-41) (Notice of Filing of Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To List and Trade Options on a Nasdaq-100 Volatility Index).

²⁰ 15 U.S.C. 78f(b).

²¹ 15 U.S.C. 78f(b)(5).

Also, in the event a trading halt caused Market Makers to not submit a Valid Width Quote in certain components during the Opening Process, the alternative methodology would look forward to obtain a value. Also, the Exchange would utilize a quote from the Opening Process only in the event an options series was able to open. If the Opening Process did not complete for an options series, there would be no value to obtain for a component during a look back.²²

This method would continue to assess the entire field of NDX options prices each second to select specific listed NDX options to obtain the prices of synthetic precisely at-the-money options. As with the initial settlement window, since the market is subject to constant change during three hundred individual one-second time periods for which listed options will be included in Closing VWAP, market participants cannot predict which options components will be included because that would entail predicting where the NDX price level (a function of predicting the price of all one-hundred component stocks) will be at the end of each of the three hundred individual one-second time periods. The Exchange reiterates that it is unlikely that the Volatility Index Closing VWAP could be manipulated. In particular, because the thirty-two component Volatility Index option inputs are reviewed each second as the market changes to determine the at-the-money strikes (meaning that Volatility Index components could change 300 times during the settlement period), market participants could manipulate the Closing VWAP only if they could replicate such value by guessing exact market moves over an extended period of 300 million microseconds. Because the likelihood of replication is extremely low, the Exchange believes that it is unlikely the Closing VWAP could be manipulated. Similarly, with respect to the look back period, it would be unlikely that manipulation could occur as the historical information would only be utilized in the event that liquidity was unavailable in the original observation window, which contains options components which cannot be predicted. Nonetheless, the Exchange, in its normal course of surveillance, will monitor for any potential manipulation of the Volatility Index Closing VWAP and monitor the integrity of the Volatility Index by analyzing trades, quotations, and orders that affect any of the 300 calculated reference prices for

²² The Closing Settlement Period occurs within seconds of the completion of the Opening Process.

any of the NDX option series used for the Closing VWAP for potential manipulation on the Exchange.

Utilizing a time period of one second to acquire a new observation window would allow the Exchange to utilize an observation window closest in time to the original window. Also, moving forward in increments of one second, as necessary, would serve to methodically move through the trading day for a potential observation window that would satisfy the Exchange's liquidity requirements.

The Exchange's proposal to amend the term "executed orders" to exclude out-of-sequence and late trades is consistent with the Act as these values may represent potential stale data in the Closing VWAP calculation. The Exchange believes the midpoint better reflects the price of a component.

Finally, the Exchange's proposal to amend current Options 4A, Section 12(b)(6)(D)(II) to remove the 12:00 p.m. deadline for publishing a settlement value is consistent with the Act because a re-opening could occur anytime during the trading day and, therefore, citing specifically to a 12:00 p.m. timeframe does not consider all possible scenarios. Further, specifically indicating a trading halt of the Nasdaq-100 index options in the rule text is more precise as the impact to the Nasdaq-100 index options is a direct concern for VOLQ. The proposed language more directly expands upon the manner in which the Closing VWAP will be handled in the event of a trading halt.

B. Self-Regulatory Organization's Statement on Burden on Competition

This proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed alternative observation windows will facilitate the listing and trading of the Volatility Index by ensuring liquidity for each of the option components. The proposed structure will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

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 (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (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-Phlx-2021-56 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-Phlx-2021-56. 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-Phlx-2021-56 and should be submitted on or before October 28, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21869 Filed 10-6-21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93227; File No. 4-698]

Joint Industry Plan; Notice of Designation of a Longer Period for Commission Action on a Proposed Amendment to the National Market System Plan Governing the Consolidated Audit Trail

October 1, 2021.

On March 31, 2021, the Operating Committee for Consolidated Audit Trail, LLC ("CAT LLC" or the "Company"), on behalf of the following parties to the National Market System Plan Governing the Consolidated Audit Trail (the "CAT NMS Plan" or "Plan"): ¹ BOX Exchange LLC; Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe Exchange, Inc., Financial Industry Regulatory Authority, Inc., Investors Exchange LLC, Long-Term Stock Exchange, Inc., Miami International Securities Exchange LLC, MEMX, LLC, MIAX Emerald, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The NASDAQ Stock Market LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (collectively, the "Participants," "self-regulatory organizations," or "SROs") filed with the Securities and Exchange Commission ("SEC" or "Commission")

²³ 17 CFR 200.30-3(a)(12).

¹ The CAT NMS Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Exchange Act and the rules and regulations thereunder. See Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696 (November 23, 2016).

pursuant to Section 11A(a)(3) of the Securities Exchange Act of 1934 (“Exchange Act”),² and Rule 608 thereunder,³ a proposed amendment (“Proposed Amendment”) to the CAT NMS Plan to implement a revised funding model for the consolidated audit trail (“CAT”) and to establish a fee schedule for Participant CAT fees in accordance with the Proposed Funding Model. The Proposed Amendment was published for comment in the **Federal Register** on April 21, 2021.⁴

On July 20, 2021, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Amendment.⁵ Rule 608(b)(2)(i) of Regulation NMS provides that such proceedings shall be concluded within 180 days of the date of publication of notice of the plan or amendment and that the time for conclusion of such proceedings may be extended for up to 60 days (up to 240 days from the date of notice publication) if the Commission determines that a longer period is appropriate and publishes the reasons for such determination or the plan participants consent to the longer period.⁶ The 180th day after publication of the Notice for the Proposed Amendment is October 18, 2021. The Commission is extending this 180-day period.

The Commission finds that it is appropriate to designate a longer period within which to conclude proceedings regarding the Proposed Amendment so that it has sufficient time to consider the Proposed Amendment and the comments received. Accordingly, pursuant to Rule 608(b)(2)(i) of Regulation NMS,⁷ the Commission designates December 17, 2021, as the date by which the Commission shall conclude the proceedings to determine whether to approve or disapprove the Proposed Amendment (File No. 4-698).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21868 Filed 10-6-21; 8:45 am]

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² 15 U.S.C 78k-1(a)(3).

³ 17 CFR 242.608.

⁴ See Notice of Filing of Amendment to the National Market System Plan Governing the Consolidated Audit Trail, Release No. 91555 (April 14, 2021), 86 FR 21050 (“Notice”).

⁵ See Securities Exchange Act Release No. 92451 (July 20, 2021), 86 FR 40114 (July 26, 2021) (“OIP”). Comments received in response to the Notice and OIP can be found on the Commission’s website at <https://www.sec.gov/comments/4-698/4-698-a.htm>.

⁶ See 17 CFR 242.608(b)(2)(i).

⁷ *Id.*

⁸ 17 CFR 200.30-3(a)(85).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93228; File No. SR-NYSEARCA-2021-86]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Rule 7.12-E

October 1, 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 September 30, 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 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 extend the pilot related to the market-wide circuit breaker in Rule 7.12-E to the close of business on March 18, 2022. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rule 7.12-E to the close of business on March 18, 2022.

Background

The Market-Wide Circuit Breaker (“MWCBS”) rules, including the Exchange’s Rule 7.12-E, provide an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when cash equities securities experience extreme market-wide declines. The MWCBS rules are designed to slow the effects of extreme price declines through coordinated trading halts across both cash equity and equity options securities markets.

The cash equities rules governing MWCBS were first adopted in 1988 and, in 2012, all U.S. cash equity exchanges and FINRA amended their cash equities uniform rules on a pilot basis (the “Pilot Rules,” *i.e.*, Rule 7.12-E (a)-(d)).⁴ The Pilot Rules currently provide for trading halts in all cash equity securities during a severe market decline as measured by a single-day decline in the S&P 500 Index (“SPX”).⁵ Under the Pilot Rules, a market-wide trading halt will be triggered if SPX declines in price by specified percentages from the prior day’s closing price of that index. The triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. and before 3:25 p.m. would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. would not halt market-wide trading. (Level 1 and Level 2 halts may occur only once a day.) A market decline that triggers a Level 3 halt at any time during the trading day would halt market-wide trading for the remainder of the trading day.

The Commission approved the Pilot Rules, the term of which was to

⁴ See Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR-BATS-2011-038; SR-BYX-2011-025; SR-BX-2011-068; SR-CBOE-2011-087; SR-C2-2011-024; SR-CHX-2011-30; SR-EDGA-2011-31; SR-EDGX-2011-30; SR-FINRA-2011-054; SR-ISE-2011-61; SR-NASDAQ-2011-131; SR-NSX-2011-11; SR-NYSE-2011-48; SR-NYSEAmex-2011-73; SR-NYSEArca-2011-68; SR-Phlx-2011-129) (“Pilot Rules Approval Order”).

⁵ The rules of the equity options exchanges similarly provide for a halt in trading if the cash equity exchanges invoke a MWCBS Halt. *See, e.g.*, NYSE Arca Rule 6.65-O(d)(4).

coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the “LULD Plan”),⁶ including any extensions to the pilot period for the LULD Plan.⁷ In April 2019, the Commission approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.⁸ In light of the proposal to make the LULD Plan permanent, the Exchange amended Rule 7.12–E to untie the pilot’s effectiveness from that of the LULD Plan and to extend the pilot’s effectiveness to the close of business on October 18, 2019.⁹ The Exchange then filed to extend the pilot for an additional year to the close of business on October 18, 2020,¹⁰ and later, on October 18, 2021.¹¹

The Exchange now proposes to amend Rule 7.12–E to extend the pilot to the close of business on March 18, 2022. This filing does not propose any substantive or additional changes to Rule 7.12–E.

The MWCB Task Force and the March 2020 MWCB Events

In late 2019, Commission staff requested the formation of a MWCB Task Force (“Task Force”) to evaluate the operation and design of the MWCB mechanism. The Task Force included representatives from the SROs, the Commission, CME, the Commodity Futures Trading Commission (“CFTC”), and the securities industry and conducted several organizational meetings in December 2019 and January 2020.

In Spring 2020, the MWCB mechanism proved itself to be an effective tool for protecting markets through turbulent times. In March 2020, at the outset of the worldwide COVID–19 pandemic, U.S. equities markets experienced four MWCB Level 1 halts,

on March 9, 12, 16, and 18, 2020. In each instance, the markets halted as intended upon a 7% drop in the S&P 500 Index, and resumed as intended 15 minutes later.

In response to these events, in the Spring and Summer of 2020, the Task Force held ten meetings that were attended by Commission staff, with the goal of performing an expedited review of the March 2020 halts and identifying any areas where the MWCB mechanism had not worked properly. Given the risk of unintended consequences, the Task Force did not recommend changes that were not rooted in a noted deficiency. The Task Force recommended creating a process for a backup reference price in the event that SPX were to become unavailable, and enhancing functional MWCB testing. The Task Force also asked CME to consider modifying its rules to enter into a limit-down state in the futures pre-market after a 7% decline instead of 5%. CME made the requested change, which became effective on October 12, 2020.¹²

The MWCB Working Group’s Study

On September 17, 2020, the Director of the Commission’s Division of Trading and Markets asked the SROs to conduct a more complete study of the design and operation of the Pilot Rules and the LULD Plan during the period of volatility in the Spring of 2020.

In response to the request, the SROs created a MWCB “Working Group” composed of SRO representatives and industry advisers that included members of the advisory committees to both the LULD Plan and the NMS Plans governing the collection, consolidation, and dissemination of last-sale transaction reports and quotations in NMS Stocks. The Working Group met regularly from September 2020 through March 2021 to consider the Commission’s request, review data, and compile its study. The Working Group’s efforts in this respect incorporated and built on the work of an MWCB Task Force.

The Working Group submitted its study to the Commission on March 31, 2021 (the “Study”).¹³ In addition to a timeline of the MWCB events in March 2020, the Study includes a summary of the analysis and recommendations of

the MWCB Task Force; an evaluation of the operation of the Pilot Rules during the March 2020 events; an evaluation of the design of the current MWCB system; and the Working Group’s conclusions and recommendations.

In the Study, the Working Group concluded: (1) The MWCB mechanism set out in the Pilot Rules worked as intended during the March 2020 events; (2) the MWCB halts triggered in March 2020 appear to have had the intended effect of calming volatility in the market, without causing harm; (3) the design of the MWCB mechanism with respect to reference value (SPX), trigger levels (7%/13%/20%), and halt times (15 minutes) is appropriate; (4) the change implemented in Amendment 10 to the Plan to Address Extraordinary Market Volatility (the “Limit Up/Limit Down Plan” or “LULD Plan”) did not likely have any negative impact on MWCB functionality; and (5) no changes should be made to the mechanism to prevent the market from halting shortly after the opening of regular trading hours at 9:30 a.m.

In light of the foregoing conclusions, the Working Group also made several recommendations, including that the Pilot Rules should be permanent without any changes.¹⁴

Proposal To Extend the Operation of the Pilot Rules Pending the Commission’s Consideration of the New York Stock Exchange LLC’s Filing To Make the Pilot Rules Permanent

On July 16, 2021, the Exchange’s affiliate, the New York Stock Exchange (“NYSE”), proposed a rule change to make the Pilot Rules permanent, consistent with the Working Group’s recommendations.¹⁵ On August 27, 2021, the Commission extended its time to consider the proposed rule change to October 20, 2021.¹⁶ The Exchange now proposes to extend the expiration date of the Pilot Rules to the end of business on March 18, 2022.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁸ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and

⁶ See Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

⁷ See Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSEArca–2011–68) (Approval Order); and 68785 (January 31, 2013), 78 FR 8646 (February 6, 2013) (SR–NYSEArca–2013–06) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Delaying the Operative Date of a Rule Change to Exchange Rule 7.12–E).

⁸ See Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

⁹ See Securities Exchange Act Release No. 85561 (April 9, 2019), 84 FR 15262 (April 15, 2019) (SR–NYSEArca–2019–23).

¹⁰ See Securities Exchange Act Release No. 87017 (September 19, 2019), 84 FR 50543 (September 25, 2019) (SR–NYSEArca–2019–66).

¹¹ See Securities Exchange Act Release No. 90136 (October 8, 2020), 85 FR 65082 (October 14, 2020) (SR–NYSEArca–2020–89).

¹² See https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20-392_1.pdf; https://www.cmegroup.com/content/dam/cmegroup/market-regulation/rule-filings/2020/9/20-392_2.pdf.

¹³ See *Report of the Market-Wide Circuit Breaker (“MWCB”) Working Group Regarding the March 2020 MWCB Events*, submitted March 31, 2021 (the “Study”), available at https://www.nyse.com/publicdocs/nyse/markets/nyse/Report_of_the_Market-Wide_Circuit_Breaker_Working_Group.pdf.

¹⁴ See *id.* at 46.

¹⁵ See Securities Exchange Act Release No. 92428 (July 16, 2021), 86 FR 38776 (July 22, 2021) (SR–NYSE–2021–40).

¹⁶ See Securities Exchange Act Release No. 92785A (August 27, 2021), 86 FR 50202 (September 7, 2021) (SR–NYSE–2021–40).

¹⁷ 15 U.S.C. 78f(b).

¹⁸ 15 U.S.C. 78f(b)(5).

perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The market-wide circuit breaker mechanism under Rule 7.12–E is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional five months would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from Pilot Rules should continue on a pilot basis because they will promote fair and orderly markets and 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 because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁹ and Rule 19b–4(f)(6) thereunder.²⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)²¹ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),²² the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange asked that the Commission waive the 30 day operative delay so that the proposal may become operative immediately upon filing. Extending the pilot Rules' effectiveness to the close of business on March 18, 2022 will extend the protections provided by the Pilot Rules, which would otherwise expire in less than 30 days. Waiver of the operative delay would therefore permit uninterrupted continuation of the MWCB pilot while the Commission reviews the Exchange's proposed rule change to make the Pilot Rules permanent. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.²³

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

¹⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

²⁰ 17 CFR 240.19b–4(f)(6).

²¹ 17 CFR 240.19b–4(f)(6).

²² 17 CFR 240.19b–4(f)(6)(iii).

²³ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

under Section 19(b)(2)(B)²⁴ 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–2021–86 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–2021–86. 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–2021–86 and

²⁴ 15 U.S.C. 78s(b)(2)(B).

should be submitted on or before October 28, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-21871 Filed 10-6-21; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17210 and #17211; MONTANA Disaster Number MT-00154]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Montana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Montana (FEMA—4623—DR), dated 09/30/2021.

Incident: Richard Spring Fire.

Incident Period: 08/08/2021 through 08/20/2021.

DATES: Issued on 09/30/2021.

Physical Loan Application Deadline Date: 11/29/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/30/2022.

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 President's major disaster declaration on 09/30/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Rosebud and the Northern Cheyenne Indian Reservation.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i> Non-Profit Organizations with Credit Available Elsewhere ...	2.000

	Percent
Non-Profit Organizations without Credit Available Elsewhere	2.000
<i>For Economic Injury:</i> Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17210 5 and for economic injury is 17211 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2021-21890 Filed 10-6-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17208 and #17209; NEW HAMPSHIRE Disaster Number NH-00056]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of New Hampshire

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of New Hampshire (FEMA—4622—DR), dated 09/30/2021.

Incident: Severe Storm and Flooding.

Incident Period: 07/17/2021 through 07/19/2021.

DATES: Issued on 09/30/2021.

Physical Loan Application Deadline Date: 11/29/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/30/2022.

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 President's major disaster declaration on 09/30/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cheshire.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i> Non-Profit Organizations With Credit Available Elsewhere ...	2.000
Non-Profit Organizations Without Credit Available Elsewhere	2.000
<i>For Economic Injury:</i> Non-Profit Organizations Without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17208 6 and for economic injury is 17209 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2021-21897 Filed 10-6-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration Number #17212 Disaster Number #ZZ-00017]

The Entire United States and U.S. Territories; Military Reservist Economic Injury Disaster Loan Program (MREIDL)

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of the Military Reservist Economic Injury Disaster Loan Program (MREIDL), dated 10/01/2021.

DATES: Issued on 10/01/2021.

Mreidl Loan Application Deadline Date: 1 year after the essential employee is discharged or released from active service.

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: This notice establishes the application filing period for the Military Reservist Economic Injury Disaster Loan Program (MREIDL).

Effective 10/01/2021, small businesses employing military reservists

²⁵ 17 CFR 200.30-3(a)(12).

may apply for economic injury disaster loans if those employees are ordered to perform active service for a period of more than 30 consecutive days, and those employees are essential to the success of the small businesses' daily operations.

The purpose of the MREIDL program is to provide funds to an eligible small business to meet its ordinary and necessary operating expenses that it could have met, but is unable to meet, because an essential employee was ordered to perform active service for more than 30 consecutive days in his or her role as a military reservist. These loans are intended only to provide the amount of working capital needed by a small business to pay its necessary obligations as they mature until operations return to normal after the essential employee is released from active service. For information/ applications contact 1-800-659-2955 or visit www.sba.gov.

Applications for the Military Reservist Economic Injury Disaster Loan Program may be filed at the above address.

The Interest Rate for eligible small businesses is 2.855.

The number assigned is 17212 0. (Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021-21968 Filed 10-6-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17206 and #17207; UTAH Disaster Number UT-00087]

Administrative Declaration of a Disaster for the State of Utah

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Utah dated 10/01/2021.

Incident: Severe Storms and Flooding.
Incident Period: 08/01/2021.

DATES: Issued on 10/01/2021.

Physical Loan Application Deadline Date: 11/30/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 07/01/2022.

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: Iron.

Contiguous Counties:

Utah: Beaver, Garfield, Kane, Washington.

Nevada: Lincoln.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	3.125
Homeowners without Credit Available Elsewhere	1.563
Businesses with Credit Available Elsewhere	5.710
Businesses without Credit Available Elsewhere	2.855
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	2.855
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17206 6 and for economic injury is 17207 0.

The States which received an EIDL Declaration # is Nevada, Utah.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2021-21909 Filed 10-6-21; 8:45 a.m.]

BILLING CODE 8026-03-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2021-0017]

Notice of Intent To Prepare an Environmental Impact Statement for Proposed Highway Improvements in Brunswick County, North Carolina and Horry County, South Carolina

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

ACTION: Notice of Intent to Prepare an Environmental Impact Statement.

SUMMARY: The FHWA is issuing this Notice of Intent (NOI) to solicit comments and advise the public, agencies, and stakeholders of an Environmental Impact Statement (EIS) that will be prepared to study the effects of a proposed project for improvements to SC 31 starting near Little River, Horry County, South Carolina and running northeast to US 17, in an area between Calabash and Shallotte, Brunswick County, North Carolina. This project is called the "Carolina Bays Parkway Extension" and is North Carolina Department of Transportation (NCDOT) Project No. R-5876 and South Carolina Department of Transportation (SCDOT), Project No. P029554. NCDOT is administering the development of this project in cooperation with SCDOT and other participating agencies. This notice contains a summary of the information as required in the Council on Environmental Quality (CEQ) National Environmental Policy Act (NEPA) regulations. This NOI should be reviewed together with the Supplementary NOI Information document which contains important details about the proposed project.

DATES: Comments on the NOI or the Supplementary NOI Information document must be received on or before November 8, 2021.

ADDRESSES: This NOI and the Supplementary NOI Information document are available in the docket referenced above at www.regulations.gov and on the project website located at <https://www.ncdot.gov/projects/carolina-bays-parkway>. A copy of the NOI and Supplementary NOI Information document can also be mailed by sending a request to the following address: U.S. Department of Transportation, Federal Highway Administration, Terry Sanford Federal Building, ATTN: Clarence W. Coleman, P.E., Preconstruction and Environment Director, RE: Carolina Bays Parkway Extension NOI, 310 New Bern Avenue, Suite 410, Raleigh, NC 27601.

Please limit any comments or questions to the information contained in this notice or the Supplementary NOI information document. Questions or comments should be posted to the docket found at www.regulations.gov under number FHWA-2021-0017. Otherwise they may also be submitted by email to Carolina-Bays-Pkwy@publicinput.com or by calling (855) 925-2801 and entering project code 7734 when prompted. All comments

received by the close of comments will be posted to the docket.

All submissions should include the agency name and the docket number that appears in the heading of this Notice. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Clarence W. Coleman, P.E., Director of Preconstruction, Federal Highway Administration, 310 New Bern Avenue, Suite 410, Raleigh, North Carolina 27601–1418, Telephone: (919) 747–7014; or Mr. D. Chad Kimes, P.E., North Carolina Department of Transportation, Division 3 Engineer, 5501 Barbados Boulevard, Castle Hayne, North Carolina 28429, Telephone: (910) 675–0143.

SUPPLEMENTARY INFORMATION: The environmental review of transportation alternatives for the US 17 corridor will be conducted in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321, *et seq.*), 23 U.S.C. 139, CEQ regulations implementing NEPA (40 CFR 1500–1508), FHWA regulations implementing NEPA (23 CFR 771.101–771.139), and all applicable Federal, State, and local governmental laws and regulations.

FHWA, in cooperation with NCDOT and SCDOT, will prepare an EIS addressing proposed improvements along the US 17 corridor located in the coastal regions of South Carolina and North Carolina.

Purpose and Need

The primary purpose of the project is to improve the transportation network in the study area by enhancing mobility and connectivity for traffic moving in and through the project area. Mobility refers to the movement of people or goods, and connectivity refers to the density of connections in road networks and the directness of links. Many intersections and roadway segments in the study area are expected to either approach or exceed the roadway capacity limits by 2040. The population within Horry and Brunswick counties has steadily increased, and is expected to continue to increase, along with the number of tourists to the area. Growth in population, tourism, and supporting services has resulted in an increase in mixed-purpose traffic on area roads.

Public involvement related to the project purpose and need has occurred. A project newsletter requesting input on the project's draft purpose and need statement was distributed to property owners and residents in the project study area in December 2018. Overall,

commenters were supportive of the project and believe there is too much traffic, particularly in the summer and during evening rush hour.

The NEPA/Section 404 Merger Team, a group of representatives from various environmental, transportation, and local agencies responsible for coordinating and participating in the environmental process for this project, concurred on the purpose and need for the project at their March 19, 2019 Concurrence Point 1 (CP1) meeting.

Expected Impacts

The EIS will include the environmental impacts of seven build alternatives (Corridor Concepts 1, 1A, 2, 4, 4A, 7, and 8) carried forward for analysis, as well as the no build alternative. It will include any adverse environmental effects which cannot be avoided and any irreversible or irretrievable commitments of resources which would be involved in the proposal should it be implemented. The following is a brief summary of the range of estimated preliminary impacts that could result from the build alternatives carried forward.

With regard to the natural environment, Corridor Concepts 1, 1A, and 2 are on the lower end of the range of wetland impacts calculated, while Corridor Concepts 4 and 4A are on the higher end of the range. Concepts 1A, 4A, and 7 are on the lower end of the range of stream impacts calculated for each of the build concepts, while Concepts 1, 4, and 8 are on the higher end. Corridor Concept 8 would impact areas designated as Essential Fish Habitat. Impacts to the 100-year floodplain range between 52 acres and 214 acres with Corridor Concepts 1A and 4A on the lower end of the range and Corridor Concept 2 on the higher end. Corridor Concepts 1A and 4A each would impact approximately one acre of floodway, while the other corridor concepts would impact approximately 2.5 acres of floodway.

With regard to the human environment, Corridor Concept 8 has greater impacts to single-family residential and commercial/industrial resources than the other corridor concepts, while Corridor Concepts 7 and 8 have greater impacts to multi-family residential resources. There is a range of impacts when considering other elements of the human environment such as churches, cemeteries, and golf courses. There are no trends which would distinguish the corridor concepts when analyzing the data for physical resources such as hazardous waste sites, underground storage tanks, and electrical substations.

It should be noted these estimated impacts are based on preliminary analysis and will be further refined as more comprehensive information is obtained through detailed field studies, environmental analysis, and further roadway design.

A detailed discussion of build alternatives, along with a table describing preliminary impacts for all resources to be analyzed in the EIS, is included in the supplemental document.

Anticipated Permits and Other Authorizations

Due to anticipated impacts to streams and wetlands, the U.S. Army Corps of Engineers will need to issue a Section 404 of the Clean Water Act permit. FHWA will authorize the use of Federal funds for right of way and construction when all requirements, including NEPA compliance, are satisfied.

Pursuant to 40 CFR 1502.16, a description of the environmental impacts of the proposed action and reasonable alternatives to the proposed action and the significance of those impacts will be disclosed in the DEIS, including information on compliance with the Endangered Species Act and Section 106 of the Historic Preservation Act of 1966. The comparison of the proposed action and reasonable alternatives will be based on this discussion of the impacts.

Environmental Coordination Schedule

Environmental coordination will involve utilization of NCDOT's NEPA/Section 404 Merger Process, a synchronized review process with various Federal, State, and local agencies performing the various environmental review and permitting procedures or consultation requirements necessary for a proposed project concurrently. The process provides a forum for appropriate agency representatives to discuss and reach consensus on ways to facilitate meeting the regulatory requirements of Section 404 of the Clean Water Act (CWA) during the NEPA decision-making phase of transportation projects. The Merger Process involves interagency meetings that include FHWA as the lead Federal agency, the U.S. Army Corps of Engineers as a cooperating agency, and the following additional concurring agencies: NCDOT, SCDOT, U.S. Environmental Protection Agency (USEPA), U.S. Fish & Wildlife Service (USFWS), National Oceanic and Atmospheric Administration (NOAA) Fisheries, North Carolina Department of Environmental Quality—Division of Water Resources (NCDEQ DWR), South

Carolina Department of Health and Environmental Control (SCDHEC), North Carolina Department of Environmental Quality—Division of Coastal Management (NCDEQ DCM), SCDHEC—Ocean & Coastal Resource Management (OCRM), North Carolina Wildlife Resources Commission (NCWRC), South Carolina Department of Natural Resources (SCDNR), SCDHEC—Bureau of Water, North Carolina State Historic Preservation Office (NC SHPO), South Carolina State Historic Preservation Office (SHPO), Cape Fear Rural Transportation Planning Organization (Cape Fear RPO), Grand Strand Area Transportation Study—Metropolitan Planning Organization (GSATS MPO), and Horry County (SC).

During the Merger Process, these agencies coordinate on seven (7) concurrence points: Concurrence Point 1, Purpose and Need and Study Area Defined; Concurrence Point 2, Detailed Study Alternatives Carried Forward (DSA); Concurrence Point 2A, Bridging Decisions and Alignment Review; Concurrence Point 3: LEDPA/Preferred Alternative Selection; Concurrence Point 4A: Avoidance and Minimization; Concurrence Point 4B: 30 Percent Hydraulic Review; and Concurrence Point 4C: Permit Drawings Review. Additional information on the NCDOT NEPA/Section 404 Merger Process may be access via the following link: <https://connect.ncdot.gov/resources/Environmental/EPU/Merger/Pages/default.aspx>. The publication date of the NOI will start a two-year time clock for the agency to reach its final decision on the project (40 CFR 1501.10(a) and (b)(2)).

NCDOT is currently conducting detailed environmental analysis and preparing conceptual design plans on the alternatives carried forward for detailed study. The DEIS is scheduled to be approved and published during fall 2021, with public hearings scheduled to occur in late 2021. The Merger Team is scheduled to select the Least Environmentally Damaging Practicable Alternative during spring 2022. The Combined Final EIS is scheduled for completion early 2023 and the ROD in mid-2023. The USACE is anticipated to issue the Section 404 of the CWA permit in fall 2023. NCDOT has developed a permitting timetable that includes a schedule of decision-making milestones and EIS documentation that has been shared with Merger Team representatives. The permitting timetable for the project may be accessed in the NOI supplementary document.

Project Scoping and Alternatives Considered

Coordination with on the project began shortly following the USACE issuance of the original notice of intent to issue a Draft EIS in the **Federal Register** on January 27, 2017. A scoping meeting was on September 13, 2017. After NCDOT decided to utilize Federal funds for this project, USACE issued a Notice in the **Federal Register** to withdraw the prior Notice of Intent, and to notify the public that it would no longer be the lead Federal agency, and would not be issuing a DEIS for this project on November 29, 2018. The USACE indicated in the Notice that the project will be federally funded, and that another lead agency would issue a Notice of Intent to prepare a DEIS.

Since that time, FHWA has notified all Federal, State, local agencies on the NEPA/Section 404 Merger Team that it is the lead Federal agency. The general public has also been notified about FHWA's Federal lead agency status. The purpose of the project is to improve the transportation network in the study area by enhancing mobility and connectivity for traffic moving in and through the project area. The NEPA/Section 404 merger team concurred with the stated purpose for the project and the initial project study area in the Concurrence Point 1 meeting held on March 19, 2019.

To accommodate the study corridor footprint at some proposed interchanges and after receiving and responding to public and local officials' input, expanding the previously approved project study area is recommended. The proposed study area will allow consideration of alignments suggested during the public input process for alternatives that could achieve the project's purpose and satisfy specific transportation needs while minimizing potential impacts to important environmental features.

NCDOT and SCDOT held two public meetings in December 2019 to present and received comments on the project alternatives, corridor options developed by NCDOT and its consultant and refined by local officials and the Merger Team. The first meeting was held on December 3, 2019, in Sunset Beach, North Carolina followed by a second meeting on December 4, 2019, in Little River, South Carolina. Over 1,000 people attended the meetings and more than 1,800 comments were received.

Most of the comments received reflected corridor concept preference for the build concepts, identified potential project impacts, or suggested variations to and additional corridor concepts. A summary of the public meetings held in

December 2019 is included in the NOI Supplementary Information document.

The Merger Team reviewed several build alternative corridor concepts, and the following alternatives were carried forward for detail study at the Concurrence Point 2 meeting that occurred on May 4, 2020: Alternative 1, 1A, 2, 4, 4A, 7, and 8. Build Alternative Corridor Concepts 3, 5, 6, and 9 were eliminated from further study. The Merger Team also decided to eliminate the Transportation System Management (TSM), Transportation Demand Management (TDM), and Mass Transit Alternatives from detailed study.

Request for Comments on Information in This Notice

With this Notice, FHWA and NCDOT requests on potential alternatives and impacts, and identification of any relevant information, studies, or analyses of any kind concerning impacts affecting the quality of the human environment. Comments may be posted to the docket found at www.regulations.gov under number FHWA-2021-0017. Otherwise they may also be submitted by email to Carolina-Bays-Pkwy@publicinput.com or by calling (855) 925-2801 and entering project code 7734 when prompted.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 42 U.S.C. 4321 *et seq.*; 23 CFR part 771.

Clarence W. Coleman,

Director of Preconstruction, Raleigh, North Carolina.

[FR Doc. 2021-21967 Filed 10-6-21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year 2021 Competitive Funding Opportunity: Innovative Coordinated Access and Mobility (ICAM) Pilot Program

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for \$3.5 million in Fiscal Year (FY) 2021 funds under the Innovative Coordinated Access and

Mobility (ICAM) pilot program. This funding opportunity seeks to improve coordination to enhance access and mobility to vital community services for older adults, people with disabilities, and people of low income. As required by Federal public transportation law, funds will be awarded competitively as grants to finance innovative mobility management capital projects that will improve the coordination of transportation services and non-emergency medical transportation (NEMT) services. FTA may award additional funding that is made available to the program prior to the announcement of project selections.

DATES: Applicants must submit completed proposals for each funding opportunity through the *GRANTS.GOV* "APPLY" function by 11:59 p.m. Eastern Time December 6, 2021. Prospective applicants should register as soon as possible on the *GRANTS.GOV* website to ensure they can complete the application process before the submission deadline. Application instructions are available on FTA's website at <https://www.transit.dot.gov/funding/grants/grant-programs/access-and-mobility-partnership-grants> and in the "FIND" module of *GRANTS.GOV*. The *GRANTS.GOV* funding opportunity ID for the ICAM is FTA-2021-009-ICAM. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: Destiny Buchanan, FTA Office of Program Management; Phone: (202) 493-8018; Email: Destiny.Buchanan@dot.gov.

SUPPLEMENTARY INFORMATION:

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A. Program Description

Section 3006(b) of the Fixing America's Surface Transportation (FAST) Act (Pub. L. 114-94, Dec. 4, 2015), as extended for FY 2021 by Division B of the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. 116-159, Oct. 1, 2020), authorizes FTA to award grants for ICAM pilot projects that improve the coordination of transportation services and NEMT services projects for transportation disadvantaged populations. Transportation

disadvantaged populations include older adults, people with disabilities, and people of low income. In the FY 2021 program, FTA intends to target funding for regional and statewide mobility management capital projects that support coordination and enable comprehensive community access, including access to NEMT, for underserved groups.

The Coordinating Council on Access and Mobility (CCAM) consists of eleven Federal agencies and coordinates 130 Federal programs that may fund transportation (find the CCAM Program Inventory at <https://www.transit.dot.gov/regulations-and-guidance/ccam/about/ccam-program-inventory>). The CCAM's mission is to improve the availability, accessibility, and efficiency of transportation for targeted populations. The benefits of successful coordinated transportation systems include providing greater access to funding and enabling more cost-effective use of resources; reducing duplication and overlap in human service agency transportation services; filling service gaps in a community or geographic area; serving additional individuals within existing budgets; and providing more centralized management of existing resources.

ICAM (Federal Assistance Listing 20.513) supports FTA's strategic goals and objectives through timely and efficient investment in public transportation. This program helps fulfill the President's commitment to mobilize American ingenuity to build a modern infrastructure and an equitable, clean energy future. In addition, this NOFO will advance the goals of the President's January 20, 2021 Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.

The ICAM pilot program will improve State and regional coordination by funding regional and statewide mobility management capital projects that enable comprehensive community access, including NEMT, for underserved groups. Successful projects will prioritize coordination, including coordination with recipients of funding from Federal agencies that are members of the CCAM, that enhances access and mobility to vital community services for older adults, people with disabilities, and people of low income.

Successful applicants should coordinate to implement a multi-agency effort to improve access of human services transportation by establishing an oversight structure and increasing inter-agency coordination to adopt:

1. Consistent driver and vehicle standards;
2. Cost allocation rate(s) when clients of different programs use a single transportation service, (increasing efficiency by using the same vehicles to transport passengers whose trips are funded via different Federal programs);
3. Rate-setting methodology based on the cost allocation rate of providing transportation (allows costs to be billed or allocated appropriately to the transportation user, facilitating a more efficient use of transportation resources); and
4. Cost allocation technology (enables costs to be shared equitably among participating agencies who receive funding from a variety of Federal agencies).

Agencies often restrict their transportation services to clients of a specific program and do not permit the vehicles or services to be used by other programs or riders. This practice leads to inefficient use of resources and unused capacity. These restrictions are often attributed to Federal requirements, but compliance with Federal requirements can be achieved without such restrictions. Federally funded vehicles and transportation resources can be shared with other agencies that have a transportation role, as long as costs can be allocated appropriately. The ICAM pilot program seeks to help promote this coordination.

B. Federal Award Information

Federal public transportation law (49 U.S.C. 5338(a)(2)(E)), as extended by the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. 116-159), authorizes \$3,500,000 in FY 2021 for competitive grants under the ICAM pilot program. FTA may cap the amount a single recipient or State may receive as part of the selection process. There is no minimum or maximum grant award amount; however, FTA intends to fund as many meritorious projects as possible. FTA may award additional funding made available to the program prior to the announcement of the project selections.

Due to funding limitations, projects selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate that the proposed projects are still viable, meet all eligibility requirements, and can be completed with the amount awarded.

The ICAM grants will operate as pilots for up to 24 months. Within the first year, projects must be able to demonstrate significant progress toward increased State interagency coordination. During the 24-month span

of the project, ICAM mobility management capital funds may be used to implement a regional or statewide pilot of coordinated service delivery, to demonstrate the benefits of coordinated transportation.

C. Eligibility Information

Eligible Applicants

Eligible applicants are State departments of transportation, designated recipients for Section 5310 funds, or local governmental entities that operate a public transportation service, or their eligible subrecipients that have the authority and technical capacity to implement a regional or statewide cost allocation pilot.

Applicants must serve as the lead agency of a regional or statewide consortium that includes stakeholders from the transportation, healthcare, human service, or other sectors. Members of this consortium are eligible as subrecipients if they would otherwise be eligible subrecipients of Section 5310 funds. Further, applicants must demonstrate that the proposed project was planned through an inclusive process with the involvement of the transportation, healthcare, and human service sectors. An implementation plan and schedule must be submitted as part of the proposal.

Cost Sharing or Matching

The maximum Federal share of projects selected under the ICAM pilot program is 80 percent. The applicant must provide a non-Federal share of at least 20 percent of the project cost and must document the source of the local match in the grant application.

Eligible sources of local match include cash and in-kind contributions. In-kind contributions must be documented in the application.

Eligible Projects

Eligible projects are capital projects, as defined in 49 U.S.C. 5302(3). FTA may make grants to assist in financing innovative projects for the transportation disadvantaged that improve the coordination of transportation services and NEMT services, including: Regional or statewide mobility management projects; deployment of coordination technology; and regional or statewide projects that create or increase access to one-call/one-click centers. FTA's goal for these pilot program grants is to identify and test promising, innovative, coordinated mobility strategies other communities can replicate. Only one project may be included in each application.

D. Application and Submission Information

1. Address To Request Application Package

A complete proposal submission consists of two forms:

- SF-424 Application for Federal Assistance (downloaded from *GRANTS.GOV*); And
- Supplemental form for the FY 2021 Innovative Coordinated Access and Mobility Pilot Program (downloaded from *GRANTS.GOV* or the FTA website at <https://www.transit.dot.gov/funding/grants/grant-programs/access-and-mobility-partnership-grants>).

Applications must be submitted through *GRANTS.GOV*. Applicants can find general information for submitting applications through *GRANTS.GOV*. Mail and fax submissions will not be accepted. Applicants may also attach additional supporting information. Failure to submit the information as requested may delay or prevent review of the application.

2. Content and Form of Application Submission

i. Proposal Submission

A complete proposal submission consists of at least two forms, the SF-424 Mandatory Form and the Supplemental Form for the FY 2021 Innovative Coordinated Access and Mobility Pilot Program. The application must include responses to all sections of the SF-424 Mandatory Form and the Supplemental Form unless a section is indicated as optional. FTA will use the information on the Supplemental Form to determine applicant and project eligibility for the program and to evaluate the proposal against the selection criteria described in part E of this notice. FTA will accept only one Supplemental Form per SF-424 submission. FTA encourages States and other applicants to consider submitting a single Supplemental Form that includes multiple activities to be evaluated as a consolidated proposal. If States or other applicants choose to submit separate proposals for individual consideration by FTA, they must submit each proposal with a separate SF-424 and Supplemental Form.

Applicants may attach additional supporting information to the SF-424 submission, including, but not limited to the following examples: Letters of support, memorandums of understanding, interagency agreements, coordinated plans, project budgets, fleet status reports, or excerpts from relevant planning documents. Supporting documentation must be described and

referenced by file name in the appropriate response section of the Supplemental Form, or it may not be reviewed.

Information such as applicant name, Federal amount requested, local match amount, or description of areas served, may be requested in varying degrees of detail on both the SF-424 Form and Supplemental Form. Applicants must fill in all fields unless stated otherwise on the forms. If applicants copy information into the Supplemental Form from another source, they should verify that the Supplemental Form has fully captured pasted text and that it has not truncated the text due to character limits built into the form. Applicants should use both the "Check Package for Errors" and the "Validate Form" buttons on both forms to check all required fields. Applicants should also ensure that the Federal and local amounts specified are consistent.

ii. Application Content

The SF-424 Mandatory Form and the Supplemental Form will prompt applicants for the required information, including:

- a. Applicant Name
- b. Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number
- c. Key contact information (including contact name, address, email address, and phone)
- d. Congressional district(s) where project will take place
- e. Project Information (including title, an executive summary, and type)
- f. A detailed description of the project
- g. A detailed description of the need for the project
- h. A detailed description of how the project will support the ICAM pilot program goals to improve access to coordinated transportation services; reduce duplication of service; and enhance efficiency of the *130 Federal programs* that may fund human service transportation.
- i. Evidence that the project is consistent with State and regional planning documents including consistency with the Coordinated Public Transportation-Human Services Transportation Plan
- j. A detailed description of all project partners and their specific role in the eligible project
- k. Specific performance measures the project will use to quantify actual outcomes against expected outcomes
- l. Evidence that the applicant can provide the non-Federal cost share and details on the non-Federal match

- m. A description of the technical, legal, and financial capacity of the applicant
- n. A detailed project budget (up to 24 months)
- o. An explanation of the scalability of the project (if applicable)
- p. A detailed project timeline

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) Be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information during which the applicant has an active Federal award or an application or plan under consideration by FTA. FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. These requirements do not apply if the applicant has an exception approved by FTA under 2 CFR 25.110(c) or (d). SAM registration takes approximately 3–5 business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit <https://www.sam.gov>.

FTA will provide further instructions on registration through an introductory applicant training session. Dates and times for the training session will be posted on FTA's website.

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern Time December 6, 2021. Late applications will not be accepted. Mail and fax submissions will not be accepted.

FTA urges applicants to submit applications at least 72 hours prior to the due date to allow time to correct any problems that may have caused either *GRANTS.GOV* or FTA systems to reject the submission. Deadlines will not be extended due to scheduled website maintenance. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website.

Within 48 hours after submitting an electronic application, the applicant should receive two email messages from *GRANTS.GOV*: (1) Confirmation of

successful transmission to *GRANTS.GOV*; and (2) confirmation of successful validation by *GRANTS.GOV*. If the applicant does not receive confirmation of successful validation or receives a notice of failed validation or incomplete materials, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, applicants must include all original attachments regardless of which attachments were updated and check the box on the Supplemental Form indicating this is a resubmission.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to update their registration before submitting an application. Registration in SAM is renewed annually and persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions.

5. Funding Restrictions

Funds made available under the ICAM pilot program may only be used for capital expenditures, including mobility management, that are included in the State Transportation Improvement Plan/Transportation Improvement Plan. Eligible projects are capital projects, as defined in 49 U.S.C. 5302(3). Allowable direct and indirect expenses must be consistent with the Government-wide Uniform Administrative Requirements and Cost Principles (2 CFR part 200) and FTA Circular 5010.1E.

Funds awarded under this notice cannot be used to reimburse recipients for expenses incurred prior to FTA issuing pre-award authority. FTA intends to issue pre-award authority pursuant to 2 CFR 200.458 to incur costs for selected projects beginning on the date FTA announces recipients of the FY 2021 awards on FTA's website. Funds are only available for projects that have not incurred costs prior to the announcement of project selections on FTA's website and the corresponding issuance of pre-award authority.

6. Other Submission Requirements

FTA encourages applicants to identify scaled funding options in the event that insufficient funding is available to fund a project at the fully requested amount.

If an applicant indicates that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. The applicant must provide a clear explanation of how a reduced award would affect the project. FTA may award a lesser amount regardless of whether the applicant provides a scalable option.

E. Application Review Information

1. Criteria

FTA will evaluate proposals submitted according to the following criteria: (a) Demonstration of need; (b) demonstration of benefits; (c) planning and partnerships; (d) local financial commitment; (e) project readiness; and (f) technical, legal, and financial capacity. Each applicant is encouraged to provide a succinct, logical, and orderly response to all criteria referenced in this NOFO. Additional information may be provided to support the responses; however, any additional documentation must be directly referenced on the Supplemental Form, including the file name where the additional information can be found.

a. Demonstration of Need

FTA will evaluate proposals based on how the proposed project will address the need for regional or statewide mobility management capital projects that enable comprehensive community access, including NEMT access, for underserved groups. FTA will consider the scope of the overall need or challenge as described.

b. Demonstration of Benefits

FTA will evaluate proposals on the benefits provided by the proposed project. Benefits will be tied to the ICAM pilot program goals and objectives:

Goals:

- (1) Improve access to coordinated transportation services;
- (2) Reduce duplication of service; and
- (3) Enhance efficiency of the 130 Federal programs that may fund human service transportation.

Objectives:

- (1) Develop an inter-agency transportation coordinating work group at the regional or state-level;
- (2) The adoption of:

- a. Consistent driver and vehicle standards,
- b. Cost allocation rate(s) when clients of different programs use a single transportation service, (increasing efficiency by using the same vehicles to

transport passengers whose trips are funded via different Federal programs),

c. Rate-setting methodology based on the cost allocation rate of providing transportation (allows costs to be billed or allocated appropriately to the transportation user, facilitating a more efficient use of transportation resources), and

d. Cost allocation technology (enables costs to be shared equitably among participating agencies who receive funding from a variety of Federal agencies); and

(3) Implementation of a regional or statewide pilot of coordinated service delivery to demonstrate the benefits of coordinated transportation.

Projects will be evaluated on the ability of the proposed project to yield data demonstrating impacts on the goals of the ICAM pilot program. Projects shall include a description of how the eligible project would improve access to coordinated transportation services, reduce duplication of service, and provide innovative solutions in the region or State and include specific performance measures the eligible project will use to quantify actual outcomes against expected outcomes.

Proposals must show that the applicant will be able to provide impact data during and after the pilot project. FTA will require each successful applicant to develop projected outcomes and project performance measures. FTA requires each successful applicant to report progress toward meeting project objectives on a quarterly basis. FTA will use this data to produce the required Annual Report to Congress that contains a detailed description of the activities carried out under the pilot program, and an evaluation of the program, including an evaluation of the performance measures described.

c. Planning and Partnerships

Applicants must describe the eligible project and identify project partners and their specific role in the project. Successful projects will work collaboratively and leverage partnerships with agencies that are funding recipients of the Federal agencies that are members of the CCAM, such as the Department of Health and Human Services' Administration for Community Living, Health Resources and Services Administration, and the Centers for Medicare and Medicaid Services. A full list of CCAM agencies may be accessed by going to <https://www.transit.dot.gov/ccam/about/agencies>. Partners also may include transportation providers as well as private and nonprofit entities involved in the coordination of NEMT for the

transportation disadvantaged.

Applicants should provide evidence of strong commitment from key partners, including memoranda of agreement or letters of support from relevant State agency stakeholders and partner organizations. Any changes to the proposed partnerships will require FTA's advance approval and must be consistent with the scope of the approved project. Projects may be derived from a locally developed, coordinated public transit-human services transportation plan.

d. Local Financial Commitment

Applicants must identify the source of the local share and describe whether such funds are currently available for the project or will need to be secured if the project is selected for funding. FTA will consider the availability of the local share as evidence of local financial commitment to the project.

e. Project Readiness

FTA will evaluate the project on the proposed schedule and the applicant's demonstrated ability to implement it. Applicants should indicate the short-term, mid-term, and long-term goals for the project. Proposals must provide specific performance measures the eligible project will use to quantify actual outcomes against expected outcomes. FTA will evaluate the project based on the extent to which it was developed inclusively, incorporating meaningful involvement from key stakeholders including consumer representatives of the target groups and providers from the healthcare, transportation, and human services sectors, among others. The applicant must show significant, ongoing involvement of the project's target population.

f. Technical, Legal and Financial Capacity

FTA will evaluate proposals on the capacity of the lead agency and any partners to successfully execute the pilot effort. The lead agency must have the authority and technical capacity to implement a regional or statewide cost allocation pilot project. The applicant should have no outstanding legal, technical, or financial issues that would make this a high-risk project. FTA will evaluate each proposal (including the business plan, financial projections, and other relevant data) for feasibility and longer-term sustainability of both the pilot project as well as the proposed project at full deployment. FTA intends to select projects with a high likelihood of long-term success and sustainability.

2. Review and Selection Process

Technical evaluation committees made up of Federal staff will evaluate proposals based on the published evaluation criteria. After applying the above criteria, FTA will give priority consideration to projects that support the Government-wide Justice 40 Initiative with the goal of delivering 40 percent of the overall benefits of relevant federal investments to disadvantaged communities. For the purposes of the Justice 40 Initiative, a community is either a group of individuals living in geographic proximity to one another, or a geographically dispersed set of individuals (such as migrant workers or Native Americans), where either type of group experiences common conditions. Furthermore to determine whether a specific community is disadvantaged, an applicant should consider, but are not limited to, the following variables: Low income, high and/or persistent poverty; High unemployment and underemployment, Racial and ethnic segregation; Linguistic isolation; High housing cost burden and substandard housing; Distressed neighborhoods; High transportation cost burden and/or low transportation access; Transit dependency associated with income, disability, or lack of access to a private automobile; Disproportionate environmental burden and high cumulative impacts; Limited water and sanitation access and affordability; Disproportionate climate impacts; and High energy cost burden and low energy access. FTA will give priority consideration to applications that have considered racial equity in the planning stage and are designed with specific elements to address racial equity and overcoming barriers to opportunity for underserved communities, in support of Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Applicants should indicate which (if any) planning and policies related to racial equity and barriers to opportunity they are implementing or have implemented, along with the specific project investment details necessary for FTA to evaluate if the investments are being made either to proactively advance racial equity and remove barriers to opportunity, or to redress prior inequities and barriers to opportunity. All project investment costs for the project that are related to advancing racial equity and addressing barriers to opportunity should be summarized.

If an applicant is proposing to implement autonomous vehicles or

other innovative motor vehicle technology, the application should demonstrate that all vehicles will comply with applicable safety requirements, including those administered by the National Highway Traffic Safety Administration (NHTSA) and Federal Motor Carrier Safety Administration (FMCSA). Specifically, the application should show that vehicles acquired for the proposed project will comply with applicable Federal Motor Vehicle Safety Standards (FMVSS) and Federal Motor Carrier Safety Regulations (FMCSR). If the vehicles may not comply, the application should either (1) show that the vehicles and their proposed operations are within the scope of an exemption or waiver that has already been granted by NHTSA, FMCSA, or both agencies or (2) directly address whether the project will require exemptions or waivers from the FMVSS, FMCSR, or any other regulation and, if the project will require exemptions or waivers, present a plan for obtaining them. If applicable, FTA will also consider the extent to which the application presents a plan to address workforce impacts of autonomous vehicles or other innovative motor vehicle technology.

Prior to making an award, FTA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information Systems (FAPIIS) accessible through SAM. An applicant may review and comment on information about itself that a Federal awarding agency previously entered. FTA will consider any comments by the applicant, in addition to the other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.206, Federal Awarding Agency Review of Risk Posed by Applicants. In determining the allocation of program funds, FTA may also consider geographic diversity, diversity in the size of the transit systems receiving funding, and the applicant's receipt of other competitive awards.

F. Federal Award Administration Information

Federal Award Notices

FTA will announce the final project selections on the FTA website. Project recipients should contact their FTA Regional Office for additional information regarding allocations for projects under each program.

Administrative and National Policy Requirements

i. Pre-Award Authority

FTA will issue specific guidance to recipients regarding pre-award authority at the time of selection. FTA does not provide pre-award authority for competitive funds until projects are selected and announced on FTA's website, and there are Federal requirements that must be met before costs are incurred. For more information about FTA's policy on pre-award authority, please see the most recent Apportionment Notice at <https://www.transit.dot.gov>.

ii. Grant Requirements

Selected applicants will submit a grant application through FTA's Transit Award Management System (TrAMS) and adhere to FTA grant requirements. All competitive grants will be subject to the congressional notification and release process. All ICAM awards are subject to the requirements of the Formula Grants for the Enhanced Mobility of Seniors and Individuals with Disabilities (49 U.S.C. 5310), including those of FTA Circular "Enhanced Mobility of Seniors and Individuals with Disabilities Program Guidance and Application Instructions" (FTA.C.9070.1). All recipients must accept the FTA Master Agreement and follow the Award Management Requirements (FTA.C.5010.1E) and the labor protections required by Federal public transportation law (49 U.S.C. 5333(b)). Technical assistance regarding these requirements is available from each FTA regional office.

iii. Buy America

All capital procurements must comply with FTA's Buy America requirements (49 U.S.C. 5323(j)), which require that all iron, steel, and manufactured products be produced in the United States, and imposes minimum domestic content and final assembly requirements for rolling stock. The cost of components and subcomponents produced in the United States must be more than 70 percent of the cost of all components, and final assembly of rolling stock must occur in the United States. Any proposal that will require a waiver must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted.

iv. Disadvantaged Business Enterprise

To be eligible to bid on any FTA-assisted vehicle procurement, entities that manufacture transit vehicles or

perform post-production alterations or retrofitting must be certified Transit Vehicle Manufacturers (TVM). If a vehicle remanufacturer is responding to a solicitation for new or remanufactured vehicles with a vehicle to which the remanufacturer has provided post-production alterations or retro-fitting (e.g., replacing major components such as engine to provide a "like new" vehicle), the vehicle remanufacturer must be a certified TVM.

iv. Planning

FTA encourages applicants to engage the appropriate State departments of transportation, Regional Transportation Planning Organizations, or Metropolitan Planning Organizations in areas to be served by the project funds available under these programs.

v. Standard Assurances

If it receives an award, the applicant must assure that it will comply with all applicable Federal statutes, regulations, Executive Orders, FTA Circulars, and other Federal administrative requirements in carrying out any project supported by the FTA grant. The applicant acknowledges that it will be under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a grant if it does not have current certifications on file.

vi. Reporting

Post-award reporting requirements include submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system. An independent evaluation of the pilot program may occur at various points in the deployment process and at the end of the pilot project. In addition, FTA is responsible for producing an Annual Report to Congress that compiles evaluations of selected projects, including an evaluation of the performance measures identified by the applicants. All applicants must develop an evaluation plan to measure the success or failure of their projects and to describe any plans for broad-based implementation of successful projects. Applicants should also include any goals, targets, and indicators referenced

in their application to the project in the Executive Summary of the TrAMS application. FTA may request data and reports to support the independent evaluation and annual report.

As part of completing the annual certifications and assurances required of FTA grant recipients, a successful applicant must report on the suspension or debarment status of itself and its principals.

If the award recipient's active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of an award made pursuant to this Notice, the recipient must comply with the Recipient Integrity and Performance Matters reporting requirements described in Appendix XII to 2 CFR part 200.

G. Federal Awarding Agency Contact

For questions about applying to the pilot program outlined in this notice, please contact the FTA Program Manager, Destiny Buchanan, phone: (202) 493-8018, or email, Destiny.Buchanan@dot.gov. A TDD is available at 1-800-877-8339 (TDDFIRS). Additionally, you may visit FTA's website for this program at <https://www.transit.dot.gov/funding/grants/grant-programs/access-and-mobility-partnership-grants>.

To ensure that applicants receive accurate information about eligibility or the program, applicants are encouraged to contact FTA directly with questions, rather than through intermediaries or third parties. FTA staff also may conduct briefings on the FY 2021 competitive grants selection and award process upon request. Contact information for FTA's regional offices can be found on FTA's website at <http://www.transit.dot.gov/>.

H. Other Information

This program is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Nuria I. Fernandez,
Administrator.

[FR Doc. 2021-21969 Filed 10-6-21; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0235]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: WINSOME I (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0235 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0235 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0235, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit

comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel NIRVANA is:

—*Intended Commercial Use of Vessel:* "To be included in the offerings of a bare-boat charter company which charters privately-owned boats in the summer in Camden, Rockport, and Rockland, Maine. If to be captained, the charter company supplies captain and crew."

—*Geographic Region Including Base of Operations:* "Maine." (Base of Operations: Rockport, ME)

—*Vessel Length and Type:* 40.0' Sail

The complete application is available for review identified in the DOT docket as MARAD 2021-0235 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0235 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21926 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0232]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: GHOST (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0232 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0232 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0232, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel GHOST is:

- Intended Commercial Use of Vessel:* “Charters.”
- Geographic Region Including Base of Operations:* “Florida” (Base of Operations: Miami, FL)
- Vessel Length and Type:* 88.0’ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0232 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0232 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21923 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0229]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: RUNAWAY BUNNY (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requester’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0229 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0229 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0229, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel RUNAWAY BUNNY is:

—*Intended Commercial Use of Vessel:*

“Occasional charters, less than 10 weeks per year.”

—*Geographic Region Including Base of Operations:* “New York, Connecticut, Rhode Island, Massachusetts, New Hampshire, Maine” (Base of Operations: Newport, Rhode Island)

—*Vessel Length and Type:* 56.8’ Sail

The complete application is available for review identified in the DOT docket as MARAD 2021–0229 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary.

There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0229 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21920 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0234]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: NIRVANA (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0234 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0234 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0234, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel NIRVANA is:

—*Intended Commercial Use of Vessel:* “Tourism charter.”

—*Geographic Region Including Base of Operations:* “California and Hawaii.” (Base of Operations: Santa Barbara, CA)

—*Vessel Length and Type:* 64.0’ Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021–0234 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0234 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21925 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0233]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: PICHEA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0233 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0233 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0233, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel PICHEA is:

- Intended Commercial Use of Vessel:* “Daily and overnight time charters.”
- Geographic Region Including Base of Operations:* “Puerto Rico.” (Base of Operations: Fajardo, PR)
- Vessel Length and Type:* 39.3’ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0233 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0233 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21924 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0228]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: GRAYCIOUS (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requester’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0228 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0228 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0228, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel *Graycious* is:

- Intended Commercial Use of Vessel:* “The intention is to operate as a small charter vessel with an average of six guests for approximately 8 to 10 weeks a year in US and Caribbean waters.”
- Geographic Region Including Base of Operations:* “Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, Puerto Rico.” (Base of Operations: Lighthouse Point, FL)
- Vessel Length and Type:* 73.3’ Sail

The complete application is available for review identified in the DOT docket as MARAD 2021–0228 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected

on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0228 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21919 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0230]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SHIFT 34 (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0230 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0230 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0230, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you

if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SHIFT 34 is:

—*Intended Commercial Use of Vessel:*

“They would like to use the boat for hire for recreational fishing, diving, snorkeling, and pleasure cruising.”

—*Geographic Region Including Base of Operations:* “Florida” (Base of Operations: Deerfield Beach, FL)

—*Vessel Length and Type:* 35.0’ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0230 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an undue adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise

comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0230 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2021–21921 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0236]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MOON SHADOW (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0236 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0236 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0236, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MOON SHADOW is:

- Intended Commercial Use of Vessel:* “Day sailing charters, sunset cruises.”
- Geographic Region Including Base of Operations:* “Maryland.” (Base of Operations: Havre de Grace, MD)
- Vessel Length and Type:* 34.0’ Sail

The complete application is available for review identified in the DOT docket as MARAD 2021–0236 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0236 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21927 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0231]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: RUNNING EASY (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor’s vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 8, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0231 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0231 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0231, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel RUNNING EASY is:

—*Intended Commercial Use of Vessel:* “Intend to carry 6 or less passengers for hire.”

—*Geographic Region Including Base of Operations:* “Washington, Alaska, Oregon” (Base of Operations: Seattle, WA)

—*Vessel Length and Type:* 55.6’ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0231 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0231 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–21922 Filed 10–6–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Interest Rate Paid on Cash Deposited To Secure U.S. Immigration and Customs Enforcement Immigration Bonds

AGENCY: Departmental Offices, Treasury.

ACTION: Notice.

SUMMARY: For the period beginning October 1, 2021, and ending on December 31, 2021, the U.S. Immigration and Customs Enforcement Immigration Bond interest rate is .05 per centum per annum.

DATES: Rates are applicable October 1, 2021 to December 31, 2021.

ADDRESSES: Comments or inquiries may be mailed to Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328.

You can download this notice at the following internet addresses: <http://www.treasury.gov> or <http://www.federalregister.gov>.

FOR FURTHER INFORMATION CONTACT:

Ryan Hanna, Manager, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Service, Parkersburg, West Virginia 261006–1328 (304) 480–5120; Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328, (304) 480–5117.

SUPPLEMENTARY INFORMATION: Federal law requires that interest payments on cash deposited to secure immigration bonds shall be “at a rate determined by the Secretary of the Treasury, except that in no case shall the interest rate exceed 3 per centum per annum.” 8 U.S.C. 1363(a). Related Federal regulations state that “Interest on cash deposited to secure immigration bonds will be at the rate as determined by the Secretary of the Treasury, but in no case will exceed 3 per centum per annum or be less than zero.” 8 CFR 293.2.

Treasury has determined that interest on the bonds will vary quarterly and will accrue during each calendar quarter at a rate equal to the lesser of the average

of the bond equivalent rates on 91-day Treasury bills auctioned during the preceding calendar quarter, or 3 per centum per annum, but in no case less than zero. [FR Doc. 2015–18545]. In addition to this Notice, Treasury posts the current quarterly rate in Table 2b—Interest Rates for Specific Legislation on the TreasuryDirect website.

The Deputy Assistant Secretary for Public Finance, Gary Grippo, having reviewed and approved this document, is delegating the authority to electronically sign this document to Heidi Cohen, Federal Register Liaison for the Department, for purposes of publication in the **Federal Register**.

Heidi Cohen,

Federal Register Liaison.

[FR Doc. 2021–21904 Filed 10–6–21; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of Citizens Coinage Advisory Committee October 19, 2021, Public Meeting

ACTION: Notice of meeting.

Pursuant to United States Code, Title 31, section 5135(b)(8)(C), the United States Mint announces the Citizens Coinage Advisory Committee (CCAC) teleconference public meeting scheduled for October 19, 2021.

Date: October 19, 2021.

Time: 9:00–10:00 a.m. (ET), October 19, 2021.

Location: This meeting will occur via teleconference. Interested members of the public may dial in to listen to the meeting at (888) 330–1716;

Access Code: 1137147.

Subject: Swearing in of new member Dr. Harcourt Fuller, review of the 2021 Annual Report, and other business.

Interested persons should call the CCAC HOTLINE at (202) 354–7502 for the latest update on meeting time and access information.

The CCAC advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals; advises the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made; and makes recommendations with respect to the mintage level for any commemorative coin recommended.

For members of the public interested in listening in to the provided call number, this is a reminder that the public attendance is for listening purposes only. Any member of the public interested in submitting matters for the CCAC's consideration is invited to submit them by email to *info@ccac.gov*.

For Accommodation Request: If you need an accommodation to listen to the CCAC meeting, please contact the Diversity Management and Civil Rights Office by October 12, 2021, at 202-354-7260 or 1-888-646-8369 (TTY)

FOR FURTHER INFORMATION CONTACT:
Jennifer Warren, United States Mint
Liaison to the CCAC; 801 9th Street NW,

Washington, DC 20220; or call 202-354-7208.

(Authority: 31 U.S.C. 5135(b)(8)(C)).

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2021-21929 Filed 10-6-21; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

Vol. 86

Thursday,

No. 192

October 7, 2021

Part II

Securities and Exchange Commission

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt New Rules 6.1P-O, 6.37AP-O, 6.40P-O, 6.41P-O, 6.62P-O, 6.64P-O, 6.76P-O, and 6.76AP-O and Amendments to Rules 1.1, 6.1-O, 6.1A-O, 6.37-O, 6.65A-O and 6.96-O; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93193; File No. SR–NYSEArca–2021–47]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt New Rules 6.1P–O, 6.37AP–O, 6.40P–O, 6.41P–O, 6.62P–O, 6.64P–O, 6.76P–O, and 6.76AP–O and Amendments to Rules 1.1, 6.1–O, 6.1A–O, 6.37–O, 6.65A–O and 6.96–O

September 29, 2021.

On June 21, 2021, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b–4 thereunder,² a proposed rule change to adopt new Rules 6.1P–O (Applicability), 6.37AP–O (Market Maker Quotations), 6.40P–O (Pre-Trade and Activity-Based Risk Controls), 6.41P–O (Price Reasonability Checks—Orders and Quotes), 6.62P–O (Orders and Modifiers), 6.64P–O (Auction Process), 6.76P–O (Order Ranking and Display), and 6.76AP–O (Order Execution and Routing) and proposes amendments to Rules 1.1 (Definitions), 6.1–O (Applicability, Definitions and References), 6.1A–O (Definitions and References—OX), 6.37–O (Obligations of Market Makers), 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility), and 6.96–O (Operation of Routing Broker) to reflect the implementation of the Exchange’s Pillar trading technology on its options market.

The proposed rule change was published for comment in the **Federal Register** on July 9, 2021.³ On August 18, 2021, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.⁵ On September 28, 2021,

the Exchange filed Amendment No. 1 to the proposed rule change,⁶ which superseded the proposed rule change as originally filed in its entirety. The Commission has received no comments on the proposed rule change.

The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act⁷ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

I. The Exchange’s Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange plans to transition its options trading platform to its Pillar technology platform. In connection with the implementation of the Pillar technology, the Exchange proposes to adopt new rules, as well as certain amendments to existing rules, to reflect how options would trade on the Exchange once the Pillar technology is implemented. This Amendment 1 to SR–NYSEArca–2021–47 replaces SR–NYSEArca–2021–47 as originally filed and supersedes such filing in its entirety.

The proposed rule change, as modified by Amendment No. 1, 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, as Modified by Amendment No. 1

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

Background

The Exchange plans to transition its options trading platform to its Pillar technology platform. The Exchange’s and its national securities exchange affiliates’⁸ (together with the Exchange, the “NYSE Exchanges”) cash equity markets are currently operating on Pillar. For this transition, the Exchange proposes to use the same Pillar technology already in operation for its cash equity market. In doing so, the Exchange will be able to offer not only common specifications for connecting to both of its cash equity and equity options markets, but also common trading functions. This Amendment No. 1 supersedes the original filing in its entirety.⁹

The Exchange plans to roll out the new technology platform over a period of time based on a range of underlying symbols, anticipated for the fourth quarter of 2021. As was the case for the other NYSE Exchanges that have transitioned to Pillar, the Exchange anticipates a three-week roll-out period

⁸ The Exchange’s national securities exchange affiliates are the New York Stock Exchange LLC (“NYSE”), NYSE American LLC (“NYSE American”), NYSE National, Inc. (“NYSE National”), and NYSE Chicago, Inc. (“NYSE Chicago”).

⁹ This Amendment No. 1 provides more background information regarding the proposed rule changes, makes clarifying changes to certain proposed rules without any substantive differences as compared to the original filing, and makes the following substantive changes from the original filing: (1) Revises how the Specified Threshold would be calculated for Limit Order Price Protection in proposed Rule 6.62P–O(a)(3)(A) to include prices equal to the Reference Price; (2) revises how a Trading Collar would be assigned, as described in proposed Rule 6.62P–O(4)(A) and (B), to provide that a Trading Collar would be reassigned to an order after a trading halt, and makes related changes to proposed Rule 6.64P–O(f)(3)(A)(ii); (3) revises proposed Rule 6.62P–O(g) to describe proposed Complex Cross Orders (*i.e.*, Complex QCC Orders) and makes revisions to how a single-leg Cross Order priced at the market would trade; (4) revises proposed Rule 6.62P–O(h)(1) to specify that a Clear-the-Book Order would be entered contemporaneous with executing an order in open outcry; (5) revises proposed Rule 6.62P–O(i)(2) to specify which order with an MTS modifier would not be subject to self-trade prevention modifiers; (6) revises proposed Rule 6.62P–O to remove the proposed Non-Display Remove Modifier; (7) revises proposed Rule 6.64P(a) to add a definition for the term “Auction Price;” (8) revises proposed Rule 6.64P–O(g)(2) to provide that during a trading halt, any unexecuted quantity of an order for which the 500-millisecond Trading Collar timer has started would be cancelled; and (9) revises proposed Rule 6.76AP–O(a)(1)(A) to provide that only the first LMM quote in time priority would be eligible for the LMM Guarantee.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 92304 (June 30, 2021), 86 FR 36440 (“Notice”).

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 92696, 86 FR 47350 (August 24, 2021). The Commission designated October 7, 2021, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁶ Amendment No. 1 is available on the Commission’s website at <https://www.sec.gov/comments/sr-nysearca-2021-47/srnysearca202147-9304467-259869.pdf>.

⁷ 15 U.S.C. 78s(b)(2).

and will announce by Trader Update¹⁰ when underlying symbols will be transitioning to the Pillar trading platform. With this transition, certain rules would continue to be applicable to options overlying symbols trading on the current trading platform—the OX system,¹¹ but would not be applicable to options overlying symbols that have transitioned to trading on Pillar.

Instead, the Exchange proposes new rules to reflect how options would trade on the Exchange once Pillar is implemented. These proposed rule changes will (1) use Pillar terminology that is based on Exchange Rule 7–E Pillar terminology governing cash equity trading; (2) provide for common functionality on both its options and cash equity markets; and (3) introduce new functionality.

The Exchange notes that certain of the proposed new Pillar rules concern functionality not currently available on the OX system and that would be unique to how option contracts trade, and therefore would be new rules with no parallel version for the Exchange’s cash equity market.

Proposed Use of “P” Modifier

As proposed, new rules governing options trading on Pillar would have the same numbering as current rules that address the same functionality, but with the modifier “P” appended to the rule number. For example, Rule 6.76–O, governing Order Ranking and Display—OX, would remain unchanged and continue to apply to any trading in symbols on the OX system. Proposed Rule 6.76P–O would govern Order Ranking and Display for trading in options symbols migrated to the Pillar platform. All other current rules that have not had a version added with a “P” modifier will be applicable to how trading functions on both the OX system and Pillar. Once options overlying all symbols have migrated to the Pillar platform, the Exchange will file a

¹⁰ Trader Updates are available here: <https://www.nyse.com/trader-update/history>. Anyone can subscribe to email updates of Trader Updates, available here: <https://www.nyse.com/subscriptions>.

¹¹ “OX” refers to the Exchange’s current electronic order delivery, execution, and reporting system for designated option issues through which orders and quotes of Users are consolidated for execution and/or display. See Rule 6.1A–O(13). “OX Book” refers to the OX’s electronic file of orders and quotes, which contain all of the orders in each of the Display Order and Working Order processes and all of the Market Makers’ quotes in the Display Order Process. See Rule 6.1A–O(14). With the transition to Pillar, the Exchange would no longer use the terms “OX” or “OX Book” and rules using those terms would not be applicable to trading on Pillar. Once the transition is complete, the Exchange will file a subsequent proposed rule change to delete references to OX and OX Book from the rulebook.

separate rule proposal to delete rules that are no longer operative because they apply only to trading on the OX system.

To reflect how the “P” modifier would operate, the Exchange proposes to add rule text immediately following the title “Rule 6–O Options Trading,” and before “Rules Principally Applicable to Trading of Option Contracts” that would provide that rules with a “P” modifier would be operative for symbols that are trading on the Pillar trading platform. As further proposed, and consistent with the handling of the transition to Pillar by the Exchange’s cash equity platform, if a symbol (and the option overlying such symbol) is trading on the Pillar trading platform, a rule with the same number as a rule with a “P” modifier would no longer be operative for that symbol.¹²

The Exchange believes that adding this explanation regarding the “P” modifier in Exchange rules would provide transparency regarding which rules and definitions would be operative during the symbol migration to Pillar.

Summary of Proposed Rule Changes

In this filing, the Exchange proposes the following new Pillar rules: Rules 6.1P–O (Applicability), 6.37AP–O (Market Maker Quotations), 6.40P–O (Pre-Trade and Activity-Based Risk Controls), 6.41P–O (Price Reasonability Checks—Orders and Quotes), 6.62P–O (Orders and Modifiers), 6.64P–O (Auction Process), 6.76P–O (Order Ranking and Display), and 6.76AP–O (Order Execution and Routing). The Exchange also proposes to amend Rules 1.1 (Definitions), 6.1–O (Applicability, Definitions and References), and 6.1A–O (Definitions and References—OX) to reflect definitions that would be applicable for options trading on Pillar and make conforming amendments to Rules 6.37–O (Obligations of Market Makers), 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility), and 6.96–O (Operation of Routing Broker). These proposed rules would set forth the foundation of the Exchange’s options trading model on Pillar and, among other things, would use existing Pillar terminology currently in effect for the Exchange’s cash equity platform.

Because certain proposed rules have definitions and functions that carry forward to other proposed rules, the

¹² The Exchange used the same description when it transitioned its cash equity platform to Pillar. See Securities Exchange Act Release Nos. 75494 (July 20, 2015), 80 FR 44170 (July 24, 2015) (SR–NYSEArca–2015–38) (Approval Order) and 74951 (May 13, 2015), 80 FR 28721 (May 19, 2015) (“NYSE Arca Equities Pillar Notice”).

Exchange proposes to describe the new rules in the following order (rather than by rule number order): Definitions, applicability, ranking and display, execution and routing, orders and modifiers, market maker quotations, pre-trade and activity-based risk controls, price reasonability checks, and auctions.

To promote clarity and transparency, the Exchange further proposes to add a preamble to the following current rules specifying that they would not be applicable to trading on Pillar: Rule 6.1–O (Applicability, Definitions and References), 6.1A–O (Definitions and References—OX), Rule 6.37A–O (Market Maker Quotations), 6.40–O (Risk Limitation Mechanism), 6.60–O (Price Protection—Orders), 6.61–O (Price Protections—Quotes), 6.62–O (Certain Types of Orders Defined), 6.64–O (OX Opening Process), 6.76–O (Order Ranking and Display—OX), 6.76A–O (Order Execution—OX), 6.88–O (Directed Orders), and 6.90–O (Qualified Contingent Crosses).

As discussed in greater detail below, the Exchange is not proposing fundamentally different functionality applicable to options trading on Pillar than on the OX system. However, with Pillar, the Exchange would introduce new terminology, and as applicable, new or updated functionality that would be available for options trading on the Pillar platform.

The Exchange notes that new rules relating to electronic complex trading on Pillar are addressed in a separate proposed rule change.¹³

Proposed Rule Changes

Rule 1.1—Definitions

Rule 1.1 sets forth definitions that are applicable to both the Exchange’s cash equity and options markets. Rule 6.1–O(b) sets forth definitions that are applicable to the trading of option contracts on the Exchange. Rule 6.1A–O sets forth definitions that are applicable to trading on the Exchange’s current OX system. In connection with the transition of options trading to Pillar, the Exchange proposes to copy the definitions currently set forth in Rules 6.1–O and 6.1A–O into Rule 1.1, with changes as described below. This proposed rule change would streamline the Exchange’s rules by consolidating definitions that would be applicable for trading on Pillar into Rule 1.1. Once the transition to Pillar is complete, the

¹³ See Securities Exchange Act Release No. 92563 (August 4, 2021), 86 FR 43704 (August 10, 2021) (Notice of proposed Rule 6.91P–O, regarding complex order trading on Pillar) (“Complex Pillar Notice”).

Exchange will file a subsequent proposed rule change to delete current Rules 6.1–O and 6.1A–O.

In connection with adding definitions to Rule 1.1, the Exchange proposes to delete the sub-paragraph numbering currently set forth in Rule 1.1. The Exchange does not believe that the sub-paragraph numbering is necessary because the definitions are organized in alphabetical order and would continue to be organized in alphabetical order. In addition, removing the sub-paragraph numbering would make any future amendments to Rule 1.1 easier to process as any new definitions would simply be added in alphabetical order.

Certain definitions in Rule 1.1 currently specify that they are only for “equities” trading. With the proposed consolidation of definitions, some of those definitions will become applicable to both options and cash equity trading, and others will continue to be applicable only to cash equity trading. With the proposed consolidation, the Exchange proposes to remove existing language limiting those definitions to “equities” traded on the Exchange if the definition would be equally applicable to options trading. In addition, to the extent that a proposed definition would continue to be applicable only to cash equity trading, the Exchange proposes to make a global change to update references to “equities” traded on the Exchange to “cash equity securities” traded on the Exchange. The Exchange believes these proposed modifications would add clarity and consistency to Exchange rules.

The Exchange proposes the following amendments to Rule 1.1.

First, definitions set forth in Rule 6.1–O(b) would be added to Rule 1.1 in alphabetical order with certain differences described in greater detail below.¹⁴ To promote clarity, if the definition that is being copied is not

¹⁴ Rule 6.1–O(b) has definitions for: Options Clearing Corporation, Rules of the Options Clearing Corporation, Clearing Member, Participating Exchange, Option Contract, Exchange Option Transaction and Exchange Transaction, Type of Option, Call, Put, Class of Options, Series of Options, Option Issue, Underlying Stock or Underlying Security, Exercise Price, Aggregate Exercise Price, Expiration Month, Expiration Date, Long Position, Short Position, Opening Purchase Transaction, Opening Writing Transaction, Closing Sale Transaction, Closing Purchase Transaction, Covered, Uncovered, Outstanding, Primary Market, Options Trading, Customer, Trading Crowd, Foreign Broker/Dealer, Exchange-Traded Fund Share, Quote with Size, Trading Official, Non-OTP Firm or Non-OTP Holder Market Maker, Firm, Consolidated Book, Crowd Participants, Electronic Order Capture System, Short Term Option Series, and Quarterly Options Series. Unless otherwise specified, the Exchange proposes to copy the definitions from Rule 6.1–O(b) to Rule 1.1 without any differences.

specifically about options trading, the Exchange proposes to add an introductory clause to the definition to specify that the term is for options traded on the Exchange. The Exchange does not propose to copy the definition of “Quote with Size,” which is currently defined in Rule 6.1–O(b)(33), to Rule 1.1 because that term would not be used in the Pillar rules, and does not propose to copy the definition of “Short Term Options Series,” because it is duplicative of Commentary .07 to Rule 6.4–O. In addition, the Exchange is not including the definition of “Foreign Broker/Dealer,” which is currently defined in Rule 6.1–O(b)(31), in Rule 1.1, as this term is not used anywhere else in Exchange rules.¹⁵ The Exchange also proposes changes to certain definitions that are being copied from Rule 6.1–O(b) to Rule 1.1, as follows:

- The Exchange proposes to amend certain definitions that are being copied to Rule 1.1 to use the term “underlying security” rather than referring separately to an “underlying stock or Exchange-Traded Fund Share.” The Exchange believes that this proposed change would not make any substantive changes because an Exchange-Traded Fund Share is a “security” as that term is defined in Rule 1.1 (and is also an NMS stock). Accordingly, the term “underlying security,” by definition, would include Exchange-Traded Fund Shares. The Exchange proposes to make this change to the following definitions that are proposed to be added to Rule 1.1: “Call,” “Class of Options,” “Covered,” “Exercise Price,” “Primary Market,” “Put,” “Option Issue,” and “Underlying Stock or Underlying Security.”¹⁶

- The Exchange proposes to streamline the definitions of “Closing Purchase Transaction,” “Closing Sale Transaction,” “Opening Purchase Transaction,” and “Opening Writing Transaction” without any substantive differences, as follows:

- The term “Closing Purchase Transaction” is currently defined in Rule 6.1–O(b)(23) to mean “an option transaction in which the purchaser’s intention is to reduce or eliminate a short position in the series of options involved in such transaction.” The proposed Rule 1.1 definition of this term would be “a transaction in a series in which the purchaser intends to

¹⁵ The Exchange is not proposing to delete the definitions of either “Quote with Size” or “Foreign Broker/Dealer” at this time as such terms would be deleted in the subsequent filing to delete Rule 6.1–O.

¹⁶ The Exchange proposes to make a similar non-substantive change to delete the term “Exchange-Traded Fund Share” in Rule 6.37–O(c).

reduce or eliminate a short position in such series.”

- The term “Closing Sale Transaction” is currently defined in Rule 6.1–O(b)(22) to mean an “option transaction in which the seller’s intention is to reduce or eliminate a long position in the series of options involved in such transaction.” The proposed Rule 1.1 definition of this term would be “a transaction in a series in which the seller intends to reduce or eliminate a long position in such series.”

- The term “Opening Purchase Transaction” is currently defined in Rule 6.1–O(b)(20) to mean “an option transaction in which the purchaser’s intention is to create or increase a long position in the series of options involved in such transaction.” The proposed Rule 1.1 definition of this term would be “a transaction in a series in which the purchaser intends to create or increase a long position in such series.”

- The term “Opening Writing Transaction” is currently defined in Rule 6.1–O(b)(21) to mean “an option transaction in which the seller’s (writer’s) intention is to create or increase a short position in the series of options involved in such transaction.” The proposed Rule 1.1 definition of this term would be “a transaction in a series in which the seller (writer) intends to create or increase a short position in such series.”

- The Exchange proposes to revise the definition of “Crowd Participants,” which is currently defined in Rule 6.1–O(b)(38) to mean “the Market Makers appointed to an option issue under Rule 6.35–O, and any Floor Brokers actively representing orders at the best bid or offer on the Exchange for a particular option series,” to not include the clause “for a particular option series” as unnecessary text.

- The Exchange proposes to revise the definition of “Electronic Order Capture System” to eliminate reference to the Commission’s order Instituting Public Administrative Proceedings Pursuant to Section 19(h)(1) of the Securities Exchange Act of 1934, Making Findings and Imposing Remedial Sanctions, which was the initial authority for the Exchange to specify requirements relating to the Electronic Order Capture System. The Exchange will continue to include requirements for the Electronic Order Capture System in its rules and does not believe it is necessary to continue to cite to the original authority for this requirement in Exchange rules.

- The Exchange proposes to streamline the definition of “Expiration

Date” to eliminate now obsolete language limiting the definition to options expiring before, on, or after February 15, 2015. In addition, the Exchange does not propose to include the following text in the Rule 1.1 definition of “Expiration Date”:

“Notwithstanding the foregoing, in the case of certain long-term options expiring on or after February 1, 2015 that the Options Clearing Corporation has designated as grandfathered, the term “expiration date” shall mean the Saturday immediately following the third Friday of the expiration month.” This rule text is now obsolete as the Exchange does not have any series trading on the Exchange with such Saturday expiration dates.

- The Exchange proposes to amend the definition of “options trading” to delete the phrase “issued by the Options Clearing Corporation.” Accordingly, the proposed Rule 1.1 definition of “options trading” would be as follows: “when not preceded by the word ‘Exchange,’ means trading in any option contract, whether or not approved for trading on the Exchange.” The Exchange believes that this proposed change is immaterial because the Exchange trades only options that have been issued by the Options Clearing Corporation, and therefore reference to the OCC is redundant and unnecessary.

- The Exchange proposes to add to the definition of “option contract” that option contracts would be included within the definition of “security” or “securities” as such terms are used in the Bylaws and Rules of the Exchange. This proposed text is copied from the last sentence of current Rule 6.1–O(a). As described below, proposed Rule 6.1P–O would not include this text. The Exchange believes that adding this text to the Rule 1.1 definition of “option contract” would promote clarity and transparency in Exchange rules by consolidating related definitions in a single location.

- The Exchange proposes to streamline the definition of “outstanding” without any substantive differences. Specifically, the Exchange proposes to replace the following Rule 6.1–O(b)(26) text, “has neither been the subject of a closing sale transaction on the Exchange or a comparable closing transaction on another participating Exchange nor been exercised nor reached its expiration date,” with the following, “has not been the subject of a closing sale transaction, exercised, or expired.” The Exchange believes that the proposed revised text has the same meaning, with more clear text.

- The Exchange proposes to modify the definition of “Trading Crowd,”

which is currently defined in Rule 6.1–O(b)(30), to include Floor Brokers, which change is consistent with how this concept is defined on other options exchanges.¹⁷

Second, definitions set forth in Rule 6.1A–O(a) would be added to Rule 1.1 in alphabetical order without any substantive differences.¹⁸ Because certain of these definitions are already set forth in Rule 1.1 for cash equity trading, the Exchange proposes to amend those existing definitions to specify that they would be applicable to options trading, and if applicable, set forth differences for options trading, as described in more detail below.

The Exchange does not propose to add the definition of “Directed Order Market Maker” to Rule 1.1 because in Pillar the Exchange would no longer support Directed Order Market Makers. In addition, the Exchange does not propose to add the definitions of “Complex BBO” or “Complex NBBO” to Rule 1.1, and instead has proposed to define terms relating to complex trading in a separate proposed rule change relating to electronic complex trading.¹⁹ The Exchange also does not propose to add options-related definitions to Rule 1.1 relating to “Sponsored Participant,” “Sponsoring OTP Firm,” and “Sponsorship Provisions” because there are currently not any Sponsored Participants trading options on the Exchange, and the Exchange does not propose to reintroduce this category of participants. As noted above, the terms “OX” and “OX Book” will not be used in Pillar rules.

Finally, in addition to definitions that are being added to Rule 1.1 without any changes from the defined terms from Rule 6.1A–O(a), the Exchange proposes the following specific changes to the definitions that would be included in the Rule 1.1 definitions:²⁰

- *Approved Person*: The Exchange proposes a non-substantive amendment to change the word “a” to “an” before “OTP Firm.”

¹⁷ See, e.g., Cboe Exchange Inc. (“Cboe”) Rule 1.1 (defining the terms “in-crowd market participant” and “ICMP” to include “an in-crowd Market-Maker, an on-floor DPM or LMM with an allocation in a class, or a Floor Broker or PAR Official representing an order in the trading crowd on the trading floor”).

¹⁸ Rule 6.1A–O(a) has definitions for: Authorized Trader, BBO, Complex BBO, Core Trading Hours, Customer, Professional Customer, Lead Market Maker, Market Center, Marketable, Market Maker, Market Maker Authorized Trader, Minimum Price Variation, NBBO, Complex NBBO, NOW Recipient, OX, OX Book, Routing Broker, Sponsored Participant, Sponsoring OTP Firm, Sponsorship Provisions, User, Directed Order Market Maker, and Order Flow Provider.

¹⁹ See Complex Pillar Notice, *supra* note 13.

²⁰ The Exchange also proposes a non-substantive amendment to the definition of “Exchange” to add a period at the end of the sentence.

- *Authorized Trader*: The Exchange proposes to amend the Rule 1.1 definition of “Authorized Trader” to remove the limitation to equities trading so that it is applicable to both cash equity securities and options traded on the Exchange, and to add that it can mean a person who may submit orders to the Exchange’s Trading Facilities on behalf of his or her OTP Holder. These proposed amendments combine the definition of Authorized Trader currently set forth in Rule 6.1A–O(a)(1) with the existing Rule 1.1 definition of Authorized Trader with one proposed substantive difference not to include reference to “Sponsored Participant” in the proposed amendment to Rule 1.1. As noted above, the Exchange does not currently have any Sponsored Participants that trade on the Exchange, and therefore, this term is no longer necessary.

- *Away Market*: The Exchange proposes to amend the Rule 1.1 definition of “Away Market” to add how that term would be used for options trading on the Exchange. As proposed, the new text would provide: “[w]ith respect to options traded on the Exchange, the term ‘Away Market’ means any Trading Center (1) with which the Exchange maintains an electronic linkage, and (2) that provides instantaneous responses to orders routed from the Exchange.” This proposed definition is based on the Rule 6.1A–O(a)(12) definition of “NOW Recipient,” which is currently defined as “any Market Center (1) with which the Exchange maintains an electronic linkage, and (2) that provides instantaneous responses to NOW Orders routed from OX. The Exchange shall designate from time to time those Market Centers that qualify as NOW Recipients and shall periodically publish such information via its website.” The Exchange proposes four non-substantive differences for the Pillar options trading definition of “Away Market”: (1) Use the Pillar term of “Away Market” instead of the term “NOW Recipient;” (2) use the term “Trading Center” instead of “Market Center;” (3) refer to “orders routed from the Exchange” instead of “NOW Orders routed from OX;” and (4) delete the text relating to the Exchange designating and publishing to its website certain Away Markets. The Exchange does not believe that this text needs to be included in the definition of Away Market because such markets are by definition those with which the Exchange maintains electronic linkage (*i.e.*, pursuant to the Options Order Protection and Locked/Crossed Market Plan).

• *BBO*: The Exchange proposes to amend the Rule 1.1 definition of “BBO” to add how that term would be used for options trading on the Exchange. As proposed, with respect to options traded on the Exchange, BBO would mean the best displayed bid or best displayed offer on the Exchange. This definition is based on the Rule 6.1A–O(a)(2)(a) definition of BBO, which currently defines BBO as the “best bid or offer on OX.” The Exchange believes that the proposed difference would add granularity to be clear that non-displayed quotes and orders would not be included in the BBO. The Exchange also proposes to use the term “Exchange” instead of “OX.”

• *Consolidated Book*: The term “Consolidated Book” is currently defined in Rule 6.1–O(b)(37)²¹ and the term “OX Book” is currently defined in Rule 6.1A–O(a)(14).²² For Pillar, the Exchange proposes to define the term “Consolidated Book” in Rule 1.1 to mean the Exchange’s electronic book of orders and quotes and that all orders and quotes that are entered into the Consolidated Book would be ranked and maintained in accordance with the rules of priority, as provided for in proposed Rule 6.76P–O. This proposed definition uses terminology similar to the existing Rule 1.1 definition of “NYSE Arca Book,” which would be amended to specify that the definition would only be for cash equity securities traded on the Exchange. The Exchange believes that the proposed definition of “Consolidated Book” for options trading on Pillar is not substantively different from either the current Rule 6.1–O definition of “Consolidated Book” or the current Rule 6.1A–O definition of “OX Book.” Rather, the changes are designed to eliminate text that would not be applicable on Pillar without changing the substance of the proposed definition and would use more streamlined text to describe the Exchange’s electronic order book. For example, the Exchange believes that the proposed use of the phrase “electronic book of orders and quotes” makes clear that the Consolidated Book would

²¹ The term “Consolidated Book” is currently defined as “the Exchange’s electronic book of limit orders for the accounts of Public Customers and broker-dealers, and Quotes with Size. All orders and Quotes with Size that are entered into the Book will be ranked and maintained in accordance with the rules of priority as provided in Rule 6.76–O. There is no limit to the size of orders or quotes that may be entered into the Consolidated Book.”

²² The term “OX Book” is currently defined as “the OX’s electronic file of orders and quotes, which contains all of the orders in each of the Display Order and Working Order Processes and all of the Market Makers’ quotes in the Display Order Process.”

include all orders and quotes, including orders from both “Public Customers and broker-dealers,” and it is not necessary to separately reference what entity may be entering orders. In addition, as noted above, the Exchange does not propose to use the term “Quote with Size” in connection with options trading on Pillar and therefore does not propose to include reference to that term in the Pillar proposed definition for “Consolidated Book.” And, as described in greater detail below in connection with proposed Rule 6.76P–O, on Pillar, the Exchange does not propose to use the terms “Display Order and Working Order Processes” and therefore these terms would not be included in the Rule 1.1 definition of Consolidated Book.

• *Core Trading Hours*: The Exchange proposes that the current definition of Core Trading Hours in Rule 1.1, which is defined as “the hours of 9:30 a.m. Eastern Time through 4:00 p.m. (Eastern Time) or such other hours as may be determined by the Exchange from time to time,” would be applicable to both cash equity securities and options trading on the Exchange. Because options trading may extend past 4:00 p.m., the Exchange proposes to amend Rule 1.1 to provide that for options traded on the Exchange, transactions may be effected on the Exchange for an equity options class until close of trading of the Primary Market for the securities underlying an options class. This proposed text is based on current Rule 6.1A–O(a)(3).²³

• *Customer and Professional Customer*: The Exchange proposes to amend Rule 1.1 to add the definitions of “Customer” and “Professional Customer.” The proposed definitions use the same text as the definitions of Customer and Professional Customer set forth in Rules 6.1A–O(a)(4) and (4A) with non-substantive differences only to specify that these definitions would be applicable for options traded on the Exchange, eliminate redundant

²³ Rule 6.1A–O(a)(3) currently defines “Core Trading Hours” to mean “the regular trading hours for business set forth in the rules of the primary markets underlying those option classes listed on the Exchange; provided, however, that transactions may be effected on the Exchange until the regular time set for the normal close of trading in the primary markets with respect to equity option classes and ETF option classes, and 15 minutes after the regular time set for the normal close of trading in the primary markets with respect to index option classes, or such other hours as may be determined by the Exchange from time to time.” The Exchange does not propose to include in the Rule 1.1 definition of Core Trading Hours for options trading the current text regarding trading that continues 15 minutes after the regular time set for the normal close of trading in the primary markets with respect to index options classes, as this is already addressed in Rule 5.20–O(a) (Trading Sessions).

headers,²⁴ and re-number the sub-paragraphs. The Exchange also proposes to include a cross-reference to the definition of a broker or dealer as defined Sections 3(a)(4) and 3(a)(5) of the Exchange Act and rules thereunder.²⁵ The Exchange believes that this specificity adds clarity and transparency to the proposed definition.

• *Floor*: The Exchange proposes to amend the Rule 1.1 definition of “Floor,” which refers to the options trading floor, to include the synonymous defined terms “Trading Floor” and “Options Trading Floor,” which terms are used throughout existing Exchange rules and make one change to remove the term “shall.” These proposed changes would add clarity and consistency to Exchange rules.

• *Lead Market Maker*: The Exchange proposes to amend the Rule 1.1 definition of “Lead Market Maker” to add how that term would be used for options trading. As proposed, the new text would provide that for options traded on the Exchange, the term “Lead Market Maker” or “LMM” would “mean a person that has been deemed qualified by the Exchange for the purpose of making transactions on the Exchange in accordance with Rule 6.82–O. Each LMM must be registered with the Exchange as a Market Maker. Any OTP Holder or OTP Firm registered as a Market Maker with the Exchange is eligible to be qualified as an LMM.” This proposed definition is based on the Rule 6.1A–O(a)(5) definition of Lead Market Maker without any substantive differences. The Exchange proposes one non-substantive difference to use the term “person” instead of “individual or entity,” because the term “person,” as currently defined in Rule 1.1, is inclusive of natural persons and entities.

• *Marketable*: The Exchange proposes to amend the Rule 1.1 definition of “Marketable” to extend it to address options traded on the Exchange by deleting the phrase “[w]ith respect to equities traded on the Exchange.”²⁶ The

²⁴ The Exchange proposes that the Rule 1.1 definition of Professional Customer would not include the sub-header of “Calculation of Professional Customer Orders” as redundant of the following text in the rule that would provide “[e]xcept as noted below, each order of any order type counts as one order for Professional order counting purposes.”

²⁵ The Exchange does not propose to add to Rule 1.1 the definition of “Customer” that is set forth in Rule 6.1–O(b)(29) as unnecessary.

²⁶ The term “Marketable” is currently defined in Rule 1.1 to mean, “[w]ith respect to equities traded on the Exchange, the term ‘Marketable’ means for a Limit Order, an order that can be immediately executed or routed. Market Orders are always considered marketable.”

current description of the term “Marketable,” for purposes of Market Orders, is the same in both Rules 1.1 and 6.1A–O(a)(7).²⁷ Accordingly, the existing Rule 1.1 text relating to term “Marketable” with respect to Market Orders would be applicable to options trading without any differences. With respect to Limit Orders, in Rule 1.1, the term “Marketable” currently means an order that can be immediately executed or routed. The current Rule 6.1A–O(a)(7) definition of the term “Marketable” for Limit Orders means when the price of the order matches or crosses the NBBO on the other side of the market. The current Rule 1.1 definition relating to Limit Orders means substantively the same thing as the current Rule 6.1A–O(a)(7) description for Limit Orders, and the Exchange proposes to use the existing Rule 1.1 definition of the term “Marketable” for both cash equity and options trading of Limit Orders. The Exchange also proposes a non-substantive amendment to add a comma after the phrase, “the term ‘Marketable’ means” and before “for a Limit Order.”

- **Market Maker:** The Exchange proposes to amend the Rule 1.1 definition of “Market Maker” to add how that term would be used for options trading. As proposed, the new text would provide that for options traded on the Exchange, the term “Market Maker” would refer “to an OTP Holder or OTP Firm that acts as a Market Maker pursuant to Rule 6.32–O.” This proposed definition is based on the Rule 6.1A–O(a)(8) definition of Market Maker, which is defined as “an OTP Holder or OTP Firm that acts as a Market Maker pursuant to Rule 6.32–O.” Accordingly, the proposed Rule 1.1 definition of the term “Market Maker” for options trading would not have any differences from the current Rule 6.1A–O definition. The Exchange also proposes to include in the Rule 1.1 definition of Market Maker for options trading that for purposes of Exchange rules, the term Market Maker includes Lead Market Makers, unless the context otherwise indicates. This proposed text is based on Rule 6.1–O(c), References, with a non-substantive difference to use the term “Exchange” instead of “NYSE Arca.” The Exchange believes this proposed change would streamline and clarify this definition by consolidating definitions relating to Market Makers in a single location.

²⁷ The term “Marketable” is currently defined in Rule 6.1A–O(a)(7) for options trading to mean “for a Limit Order, the price matches or crosses the NBBO on the other side of the market. Market orders are always considered marketable.”

- **Market Maker Authorized Trader:** The Exchange proposes to amend the Rule 1.1 definition of “Market Maker Authorized Trader” to add how that term would be used for options trading. As proposed, the new text would provide that for options traded on the Exchange, the term “Market Maker Authorized Trader” or “MMAT” would “mean an authorized trader who performs market making activities pursuant to Rule 6–O on behalf of an OTP Firm or OTP Holder registered as a Market Maker.” This proposed definition is based on the Rule 6.1A–O(a)(9) definition of Market Maker Authorized Trader without any differences.

- **Market Participant Identifier (“MPID”):** The Exchange proposes to add a new definition to Rule 1.1 for “Market Participant Identifier (‘MPID’).” This term is currently used in, but not defined in, Rules 7.19–E and 7.31–E(i)(2) for cash equities trading. Because this term would also be used for options trading on Pillar, the Exchange believes that defining this term in Rule 1.1 would promote clarity and transparency. The proposed definition would provide that “Market Participant Identifier” or “MPID” refers to the identifier assigned to the orders and quotes of a single ETP Holder, OTP Holder, or OTP Firm for the execution and clearing of trades on the Exchange by that permit holder. The definition would further provide that an ETP Holder, OTP Holder, or OTP Firm may obtain multiple MPIDs and each such MPID may be associated with one or more sub-identifiers of that MPID. The Exchange believes that using the term MPID on the Exchange for options trading would promote clarity as this is an identifier commonly used by members of exchanges and the Exchange believes that using this term for its OTP Holders and OTP Firms would promote consistency, particularly for those firms that are also ETP Holders on the Exchange.

- **Minimum Price Variation or MPV:** The Exchange proposes to amend Rule 1.1 to add the definition of “Minimum Price Variation” or “MPV” for both cash equity securities and options that are traded on the Exchange. The Exchange proposes that the term “Minimum Price Variation” or “MPV” means the minimum price variations established by the Exchange. The Exchange further proposes that the MPV for quoting cash equity securities traded on the Exchange are set forth in Rule 7.6–E. The Exchange further proposes that the MPV for quoting and trading options traded on the Exchange are set forth in Rule 6.72–O(a). The proposed definition as it

relates to options trading is based on the Rule 6.1A–O(a)(10) definition of MPV, which defines the term “Minimum Price Variation” to mean “the variations established by the Exchange pursuant to Rule 6.72–O(a).” Similar to this current rule, the proposed Rule 1.1 definition of MPV for options trading would cross reference Rule 6.72–O(a). The Exchange proposes a difference to add reference to “quoting and trading options” to distinguish how the MPV for options would be determined from how the MPV for quoting cash equity securities would be determined.

- **NBBO:** The Exchange proposes to amend the Rule 1.1 definition of “NBBO, Best Protected Bid, Best Protected Offer, Protected Best Bid and Offer (PBBO)” to add how the term NBBO would be used for options trading. The Exchange proposes that: “[w]ith respect to options traded on the Exchange, the term ‘NBBO’ means the national best bid or offer. The terms ‘NBB’ means the national best bid and ‘NBO’ means the national best offer.” This proposed definition includes the current definition of NBBO from Rule 6.1A–O(a)(11)(a), which defines that term as “the national best bid or best offer.” The Exchange proposes to add the terms “NBB” and “NBO” as clarifying terms for options trading.

In addition, the Exchange proposes that, unless otherwise specified, for options trading, the Exchange may adjust its calculation of the NBBO based on information about orders it sends to Away Markets, execution reports received from those Away Markets, and certain orders received by the Exchange. This proposed text reflects how the Exchange currently calculates the NBBO for options trading and is based on how the PBBO is calculated on the Exchange’s cash equity market, as described in Rule 7.37–E(d)(2).²⁸ The Exchange proposes that it would adjust its calculation of the NBBO for options traded on the Exchange in the same manner that the Exchange calculates the PBBO for cash equity securities traded on the Exchange. The Exchange believes that adding this detail to the proposed definition of NBBO would promote clarity and transparency in Exchange rules. The Exchange further notes that there are limited circumstances when the Exchange would not adjust its calculation of the NBBO, and would determine the NBBO for options in the same way that the Exchange determines

²⁸ See Securities Exchange Act Release No. 91564 (April 14, 2021), 86 FR 20541 (April 20, 2021) (SR–NYSEArca–2021–21) (Notice of filing and immediate effectiveness of proposed rule change to specify when the Exchange may adjust its calculation of the PBBO).

the NBBO for cash equity securities traded on the Exchange. As described in detail below, the Exchange will specify in its rules when it would be not be using an adjusted NBBO for purposes of a specific rule. The Exchange further proposes that the term “Away Market NBBO” would be subsumed in the definition of NBBO and would refer to a calculation of the NBBO that excludes the Exchange’s BBO. The term “Away Market NBBO” would be a new defined term for options trading and would promote clarity and transparency regarding whether for purposes of a specific rule, the NBBO would not include the Exchange’s BBO.²⁹

- *NYSE Arca Book*: The Exchange proposes to amend the Rule 1.1 definition of “NYSE Arca Book” to specify that this term is applicable only for cash equity securities traded on the Exchange. As noted above, the Exchange uses the term “Consolidated Book” for options traded on the Exchange and would continue to use that term on Pillar for options trading.

- *NYSE Arca Marketplace*: The Exchange proposes to amend the Rule 1.1 definition of “NYSE Arca Marketplace” to specify that this term is applicable only for cash equity securities traded on the Exchange.

- *Order Flow Provider or OFP*: The Exchange proposes to add the definition of “Order Flow Provider or OFP” to Rule 1.1 to mean “any OTP Holder that submits, as agent, orders to the Exchange.” This proposed definition is based on the Rule 6.1A–O(a)(21) definition of “Order Flow Provider” without any differences.

- *Trading Center*: The Exchange proposes to amend the Rule 1.1 definition of “Trading Center” to add how this term would be used for options trading. As proposed: “[w]ith respect to options traded on the Exchange, for purposes of Rule 6–O, the term “Trading Center” means a national securities exchange that has qualified for participation in the Options Clearing Corporation pursuant to the provisions of the rules of the Options Clearing Corporation.” This proposed definition is based on the Rule 6.1A–O(a)(6) definition of “Market Center” with a non-substantive difference to use the term “Trading Center” instead of “Market Center.”

- *User*: The Exchange proposes to amend the Rule 1.1 definition of “User” to add how this term would be used for options trading. As proposed: “[w]ith respect to options traded on the

Exchange, the term ‘User’ shall mean any OTP Holder or OTP Firm who is authorized to obtain access to the Exchange pursuant to Rule 6.2A–O.” This proposed definition is based on the Rule 6.1A–O(a)(19) definition of User, with one difference not to include the now obsolete reference to Sponsored Participant, which, as described above, is no longer used in connection with options trading.

- *User Agreement*: The Exchange proposes a non-substantive amendment to the Rule 1.1 definition of “User Agreement” to replace the term “NYSE Arca, L.L.C.” with the term the “Exchange.”

In addition to proposed amendments to Rule 1.1, the Exchange proposes to amend Rule 6.96–O to add the definition of “Routing Broker,” which is currently defined in Rule 6.1A–O(a)(15) to mean “the broker-dealer affiliate of NYSE Arca, Inc. and/or any other non-affiliate that acts as a facility of NYSE Arca, Inc. for routing orders entered into OX of OTP Holders, OTP Firms and OTP Firms’ Sponsored Participants to other Market Centers for execution whenever such routing is required by NYSE Arca Rules.” For options trading on Pillar, the Exchange proposes to define the term in Rule 6.96–O (Operation of a Routing Broker) to mean “the broker-dealer affiliate of NYSE Arca, Inc. and/or any other non-affiliate that acts as a facility of the Exchange for routing orders submitted to the Exchange to other Trading Centers for execution whenever such routing is required by NYSE Arca Rules and federal securities laws.”³⁰ The proposed rule text is based on the current definition in Rule 6.1A–O(a)(15), with non-substantive differences to streamline the definition and to use Pillar terminology. Specifically, the Exchange does not propose to include terms that would no longer be applicable to trading on Pillar, including reference to OX, Market Centers, and Sponsored Participants. The Exchange notes that including the definition of “Routing Broker” in its rule governing the operation of the routing broker is consistent with the Exchange’s cash equity rules, which also defines the term “Routing Broker” in Rule 7.45–E(a) (Operation of Routing Broker).

In connection with the proposed amendments to Rule 1.1, the Exchange proposes to add the following preamble to Rule 6.1A–O: “This Rule is not

applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.1A–O would not be applicable to trading on Pillar.

Proposed Rule 6.1P–O: Applicability

Current Rule 6.1–O sets forth the applicability, definitions, and references in connection with options trading. As noted above, the definitions in Rule 6.1–O(b) and reference to LMMs being included in the definition of Market Maker will be copied to proposed Rule 1.1 for purposes of trading on Pillar.

The Exchange proposes new Rule 6.1P–O to include only those portions of Rule 6.1–O relating to applicability of Exchange Rules that would continue to be applicable after the transition to Pillar. Proposed Rule 6.1P–O(a) would be identical to the first two sentences of current Rule 6.1–O(a). As noted above, the proposed definition of “option contract” would incorporate the final sentence of Rule 6.1–O(a), which states that option contracts are included in the definition of “security” or “securities.” Accordingly, the Exchange does not propose to include this text in proposed Rule 6.1P–O(a).

Proposed Rule 6.1P–O(b) would provide that unless otherwise stated, Exchange rules would be applicable to transactions on the Exchange in option contracts. The proposed rule is similar to Rule 6.1–O(e) because it addresses the applicability of other Exchange Rules.³¹ The Exchange proposes differences from current Rule 6.1–O(e) to eliminate obsolete and duplicative text and to streamline the proposed rule text without any substantive differences. For example, the Exchange does not believe it is necessary to identify which rules are or are not applicable to trading of option contracts because any rule with “–O” appended to it is applicable to trading of option contracts. In addition, Rule 1.1 is now applicable to trading of options contracts. And, as discussed above, the Exchange has proposed to amend the definition of “option contract” to specify that they are included in the definition of “security” or “securities.” Finally, the

³¹ Rule 6.1–O(e) provides: “*Applicability of Other Exchange Rules*. The following Rules apply to transactions on the Exchange in option contracts issued or subject to issuance by the Options Clearing Corporation: Rules 4.15–O–4.19–O, 5.1–O, 9.21–O–9.28–O and 11.6. The following Rules do not apply to transactions on the Exchange in option contracts: Rule 1.1. All other Exchange rules are applicable to transactions on the Exchange in option contracts unless the context clearly indicates otherwise. In applying the Rules of the Exchange to transactions on the Exchange in option contracts, ‘security’ or ‘securities’ includes option contracts, ‘specialist’ means Market Maker on the Options Trading Floor.”

²⁹ See, e.g., *infra*, discussion regarding proposed Rule 6.62P(a)(1)(A)(iii), which would use the term “Away Market NBBO.”

³⁰ The Exchange also proposes non-substantive amendments to Rule 6.96–O to renumber current paragraphs (a), (b), and (c), as paragraphs (b), (c), and (d).

reference in Rule 6.1–O(e) to “‘specialist’ means ‘Market Maker’” is duplicative of Rule 6.32–O, and therefore is not necessary to add to proposed Rule 6.1P–O(b).

In connection with proposed Rule 6.1P–O, the Exchange proposes to add the following preamble to Rule 6.1–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.1–O would not be applicable to trading on Pillar.

Proposed Rule 6.76P–O: Order Ranking and Display

Rule 6.76–O governs order ranking and display for the current Exchange options trading system. Proposed Rule 6.76P–O would address order ranking and display for options trading under Pillar, including accounting for the quoting activity of options Market Makers as noted below. With the transition to Pillar, the Exchange does not propose any substantive differences to how orders would be ranked and displayed on the Exchange. However, the Exchange proposes to eliminate the terminology relating to the “Display Order Process” and “Working Order Process” (each of which are described below) and instead use Pillar terminology based on Rule 7.36–E, which governs order ranking and display on the Exchange’s cash equity market.³²

The Exchange proposes a difference between proposed Pillar options rules and the existing cash equity Pillar rules to reflect that, in addition to entering orders, options Market Makers enter quotes, which cash equity market makers do not. Accordingly, when the cash equity rules refer to “orders,” the proposed options Pillar rules would refer to both “orders and quotes” to incorporate this difference between cash equity and options markets, except where specified otherwise.³³

As discussed in detail below, the Exchange believes that the proposed new rule text provides transparency with respect to how the Exchange’s price-time priority model would operate through the use of new terminology applicable to all orders and quotes on the Pillar trading platform. In addition, throughout proposed Rule 6.76P–O, the Exchange proposes to change the term “shall” to “will,” which is a stylistic

preference that would add consistency to Exchange rules.

Proposed Rule 6.76P–O(a) would set forth definitions for purposes of all of Rule 6–O (Options Trading) on the Pillar trading platform, including proposed Rule 6.76AP–O (Order Execution and Routing), described below. The proposed definitions are based on Rule 7.36–E(a) definitions for purposes of Rule 7–E cash equity trading, with differences, as noted above, to reference “orders and quotes” throughout proposed Rule 6.76P–O. The Exchange believes that these proposed definitions would provide transparency regarding how the Exchange would operate its options platform on Pillar, and serve as the foundation for how orders and modifiers would be described for options trading on Pillar, as discussed in more detail below. In addition, the Exchange believes that even with using Pillar terminology that is based on the Exchange’s cash equity rules, unless otherwise specified, the definitions that are described in these proposed rules do not differ in substance from current Rule 6.76–O relating to options trading.

- Proposed Rule 6.76P–O(a)(1) would define the term “display price” to mean the price at which an order or quote ranked Priority 2—Display Orders or Market Order is displayed, which price may be different from the limit price or working price of the order (*i.e.*, if it is a Non-Routable Limit Order or an ALO Order as described below in proposed Rule 6.62P–O(e)(1), (2), respectively). This proposed definition uses Pillar terminology based on Rule 7.36–E(a)(1). To incorporate quotes, the Exchange proposes to refer to “order or quote ranked Priority 2—Display Orders,” versus referring to “Limit Order,” as set forth in Rule 7.36–E(a)(1). The term “Priority 2—Display Orders” is described in more detail below. The Exchange also proposes a second difference compared to the Exchange’s cash equity rules to include Market Orders as interest that may have a display price (for example, as described below and consistent with current functionality, a Market Order could be displayed at its Trading Collar, which is unique to options trading and not available on the cash equity platform).

- Proposed Rule 6.76P–O(a)(2) would define the term “limit price” to mean the highest (lowest) specified price at which a Limit Order or quote to buy (sell) is eligible to trade. The limit price is designated by the User. As noted in the proposed definitions of display price and working price, the limit price designated by the User may differ from the price at which the order would be

displayed or eligible to trade. This proposed definition uses Pillar terminology based on Rule 7.36–E(a)(2), with a difference to refer to the specified price of a “Limit Order or quote,” versus referring to “Limit Order,” as set forth in Rule 7.36–E(a)(2).

- Proposed Rule 6.76P–O(a)(3) would define the term “working price” to mean the price at which an order or quote is eligible to trade at any given time, which may be different from the limit price or display price of an order. This proposed definition is based on Rule 7.36–E(a)(3), with a difference to refer to “order or quote” for purposes of determining ranking priority, versus referring solely to an “an order,” as set forth in Rule 7.36–E(a)(3). The Exchange believes that the term “working price” would provide clarity regarding the price at which an order may be executed at any given time. Specifically, the Exchange believes that use of the term “working” denotes that this is a price that is subject to change, depending on the circumstances. The Exchange will be using this term in connection with orders and modifiers, as described in more detail below.

- Proposed Rule 6.76P–O(a)(4) would define the term “working time” to mean the effective time sequence assigned to an order or quote for purposes of determining its priority ranking. The Exchange proposes to use the term “working time” in its rules for trading on the Pillar trading platform instead of terms such as “time sequence” or “time priority,” which are used in rules governing option trading on the Exchange’s current system. The Exchange believes that use of the term “working” denotes that this is a time assigned to an order for purposes of ranking and is subject to change, depending on circumstances. This proposed definition is based on Rule 7.36–E(a)(4), with a difference to refer to an “order or quote,” versus referring solely to “an order,” as set forth in Rule 7.36–E(a)(4).

- Proposed Rule 6.76P–O(a)(5) would define an “Aggressing Order” or “Aggressing Quote” to mean a buy (sell) order or quote that is or becomes marketable against sell (buy) interest on the Consolidated Book. The proposed terms would therefore refer to orders or quotes that are marketable against other orders or quotes on the Consolidated Book. These terms would be applicable to incoming orders or quotes, orders that have returned unexecuted after routing, or resting orders or quotes that become marketable due to one or more events. For the most part, resting orders or quotes will have already traded with

³² As noted herein (*see supra* note 11), the Exchange also proposes to eliminate the use of the terms “OX” and “OX Book,” as these terms would not be applicable to trading on Pillar.

³³ *See, e.g.*, proposed Rules 6.76–O(a)(1), (3), (b)–(f) (as described herein).

contra-side interest against which they are marketable.

To maximize the potential for orders or quotes to trade, the Exchange continually evaluates whether resting interest may become marketable. Events that could trigger a resting order to become marketable include updates to the working price of such order or quote, updates to the NBBO, changes to other interest resting on the Consolidated Book, or processing of inbound messages. To address such circumstances, the Exchange proposes to include in proposed Rule 6.76P–O(a)(5) that a resting order or quote may become an Aggressing Order or Aggressing Quote if its working price changes, if the NBBO is updated, because of changes to other orders or quotes on the Consolidated Book, or when processing inbound messages.

The proposed definition of an “Aggressing Order” is based on Rule 7.36–E(a)(5), with differences in the proposed rule to account for options trading, such as including the defined term “Aggressing Quote”; referring to an “order or quote” versus “an order”; referring to the Consolidated Book rather than NYSE Arca Book; and referring to the NBBO instead of the PBBO, which is not a term used in options trading. The Exchange believes that these proposed definitions would promote transparency in Exchange rules by providing detail regarding circumstances when a resting order or quote may become marketable, and thus would be an Aggressing Order or Aggressing Quote.

Under current Rule 6.76–O, bids and offers are ranked and maintained in the Display Order Process and/or the Working Order Process of the OX Book according to price-time priority. In the Display Order Process, all Limit Orders (with no other conditions), quotes, and the displayed portion of Reserve Orders (not the reserve size) are ranked in price-time priority, displayed on an anonymous basis (except as permitted by Rule 6.76A–O), and the best-ranked interest is disseminated.³⁴ In the Working Order Process, the reserve portion of Reserve Orders,³⁵ All-or-

None Orders, Stop and Stop Limit Orders and Stock Contingency Orders are ranked in price-time priority based on the limit price or, in the case of Stop and Stop Limit Orders, the stop price. As described in more detail below, proposed Rule 6.62P–O, relating to orders and modifiers, would specify whether an order or quote would be displayable, *i.e.*, ranked Priority 2 Display Orders, or non-displayable, *i.e.*, ranked Priority 3—Non-Display Orders.

Proposed Rule 6.76P–O(b) would govern the display of non-marketable Limit Orders and quotes. As proposed, the Exchange would display “all non-marketable Limit Orders and quotes ranked Priority 2—Display Orders unless the order or modifier instruction specifies that all or a portion of the order is not to be displayed,” which functionality is the same as that set forth in the first sentence of the preamble to the current Rule 6.76–O, stating that the Exchange displays “all non-marketable limit orders in the Display Order Process.” The Exchange proposes to use Pillar ranking terminology (described further below) to describe the same functionality and references to the Display Order Process would not be included.

Rule 6.76P–O(b)(1), which is substantially identical to current Rule 6.76–O(b), would provide that except as otherwise permitted in proposed new Rule 6.76AP–O (discussed below), all non-marketable displayed interest would be displayed on an anonymous basis.³⁶

Proposed Rule 6.76P–O(b)(2) is substantially identical to the second sentence of the preamble to current Rule 6.76–O, and mirroring that text, would provide that the Exchange would “disseminate current consolidated quotations/last sale information, and such other market information as may be made available from time to time pursuant to agreement between the Exchange and other Trading Centers, consistent with the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information.”³⁷

from the reserve portion, the reserve portion remains ranked based on the original time of order entry, while the displayed portion is sent to the Display Order Process with a new time-stamp. See Rule 6.76–O(a)(2)(A).

³⁶ Rule 6.76–O(b) provides that “[e]xcept as otherwise permitted by Rule 6.76A–O, all bids and offers at all price levels in the Display Order Process of the OX Book shall be displayed on an anonymous basis.”

³⁷ The second sentence of the preamble to current Rule 6.76–O states, “OX also will disseminate current consolidated quotations/last sale information, and such other market information as may be made available from time to time pursuant to agreement between the Exchange and other Market Centers, consistent with the Plan for

Finally, proposed Rule 6.76P–O(b)(3) would provide that if “an Away Market locks or crosses the Exchange BBO, the Exchange will not change the display price of any Limit Orders or quotes ranked Priority 2—Display Orders and any such orders will be eligible to be displayed as the Exchange’s BBO.” This proposed rule describes Pillar functionality, which is the same as current functionality. The Exchange believes that including this text in the proposed rules would promote clarity and granularity. In addition, this proposed concept, which is based on Rule 7.36–E(b)(4), makes clear that resting displayed interest that did not cause a locked or crossed market condition can stand its ground and maintain priority at the price at which it was originally displayed. This provision uses Pillar terminology and functionality described in Rule 7.36–E(b)(4), but does not include text from the cash equity rule providing for the treatment of displayed Limit Orders that are “marketable against protected quotations on Away Market” before “resuming trading and publishing a quote in a UTP Security following a Regulatory Halts,” because the concept of trading a security on an unlisted trading privileges basis and how a non-primary cash equity market would resume trading after a primary listing exchanges resumes trading following a trading halt is not applicable to options trading.

Proposed Rule 6.76P–O(c) would describe the Exchange’s general process for ranking orders and quotes, which process is the same as that set forth in current Rule 6.76–O(a), with differences to use Pillar ranking terminology and include additional detail related to order/quote modifiers.³⁸ As proposed, Rule 6.76P–O(c) would provide that all non-marketable orders and quotes would be ranked and maintained in the Consolidated Book according to price-time priority in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order/quote or modifier condition. Accordingly, orders and quotes would be first ranked by price. Next, at each price level, orders and quotes would be assigned a priority category, which is similar to the Exchange’s current process to assign orders and quotes as being part of either the “Display Order

Reporting of Consolidated Options Last Sale Reports and Quotation Information.” The Exchange proposes a difference to use the term “Trading Centers” instead of “Market Centers.”

³⁸ Rule 6.76–O(a) states that the Exchange ranks bids and offers “according to price-time priority, such that within each price level, all bids and offers shall be organized by the time of entry”.

³⁴ See Rule 6.76–O(a)(1)(A)–(B), (b) and (c). When the displayed portion of the Reserve Order is decremented completely, the displayed portion of the Reserve Order shall be refreshed for the displayed amount; or the entire reserve amount, if the remaining reserve amount is smaller than the displayed amount, from the reserve portion and shall be submitted and ranked at the specified limit price and the new time that the displayed portion of the order was refreshed. See Rule 6.76–O(a)(1)(B). As discussed in more detail below, the Exchange proposes to describe how Reserve Orders would function in proposed Rule 6.62P–O(d)(1).

³⁵ See Rule 6.76–O(a)(2)(A)–(E). After the displayed portion of a Reserve Order is refreshed

Process” or “Working Order Process.” Orders and quotes in each priority category would be required to be exhausted before moving to the next priority category. Within each priority category, orders and quotes would be ranked by time. These general requirements for ranking are applicable to all orders and quotes, unless an order or quote or modifier has a specified exception to this ranking methodology, as described in more detail below. The Exchange is proposing this ranking description instead of using the above-described terms of “Display Order Process” and “Working Order Process” in Rule 6.76–O. However, substantively there would be no difference in how the Exchange would rank orders and quotes on the Pillar trading platform from how it ranks orders and quotes in the current option trading system. For example, a non-displayed order would always be ranked after a displayed order at the same price, even if the non-displayed order has an earlier working time. In addition, this proposed rule would use Pillar terminology based on Rule 7.36–E(c), with differences to reflect options trading, including that the proposed rule references “non-marketable orders and quotes,” not solely “non-marketable orders,” and references the “Consolidated Book,” rather than the “NYSE Arca Book.”

Proposed Rule 6.76P–O(d) would describe how orders and quotes would be ranked based on price, which additional detail would provide transparency regarding the Exchange’s price-ranking process. Specifically, as proposed, all orders and quotes would be ranked based on the working price of an order or quote. Orders and quotes to buy would be ranked from highest working price to lowest working price and orders and quotes to sell would be ranked from lowest working price to highest working price. The rule would further provide that if the working price of an order or quote changes, the price priority of an order or quote would change. This proposed pricing priority is current functionality, but the new rule would add detail regarding the concept of “working price” and its impact on priority and would use Pillar terminology. In addition, this proposed rule uses Pillar terminology from Rule 7.36–E(d), with differences to reflect options trading to reference “orders and quotes” as opposed to solely “orders.”

Proposed Rule 6.76P–O(e) would describe the proposed priority categories for ranking purposes, which added detail and terminology would be new for option trading without any

functional differences.³⁹ As proposed, at each price, all orders and quotes would be assigned a priority category. If, at a price, there are no orders or quotes in a priority category, the next category would have first priority. The Exchange does not propose to include in Rule 6.76P–O, which sets forth the general rule regarding ranking, specifics about how one or more order or quote types may be ranked and displayed. Instead, as described in more detail below, the Exchange will address separately in new Rule 6.62P–O governing orders and modifiers which priority category correlates to different order types and modifiers. Accordingly, details regarding which proposed priority categories would be assigned to the display and reserve portions of Reserve Orders, which is currently addressed in Rule 6.76–O (a)(1)(B) and (a)(2)(A), will be addressed in proposed Rule 6.62P–O and therefore would not be included in proposed Rule 6.76P–O.⁴⁰

The proposed changes are also the same as the terms used for priority categories for cash equity trading as set forth in Rule 7.36–E(e)(1)–(3), with differences to include options-specific reference to “orders and quotes” rather than just orders as relates to interest ranked Priority 2 and 3. In addition, the Exchange does not propose to include the Priority 4—Tracking Orders category, which relates to an order type not available for option trading.

The proposed priority categories would be:

- Proposed Rule 6.76P–O(e)(1) would specify “Priority 1—Market Orders,” which provides that unexecuted Market Orders would have priority over all other same-side orders with the same working price. As described in greater detail below, a Market Order subject to a Trading Collar would be displayed on the Consolidated Book. In such circumstances, the displayed Market Order would have priority over all other resting orders at that price. Under current options trading functionality, Market Orders have priority over all other same-side orders with the same working price. The proposed level of detail and priority categorization would be new terminology for options trading and the Exchange believes that the proposed rule change would add transparency and specificity to

³⁹ See *supra* notes 34 and 35 (regarding treatment of Reserve Orders per Rule 6.76–O(a)(1)(B) and (a)(2)(A)).

⁴⁰ See, e.g., Rule 6.76–O(a)(1) and (2) (setting forth the price-time ranking and priority structure for bids and offers submitted to the Exchange, including ranking of certain order types with contingencies).

Exchange rules without changing functionality.

- Proposed Rule 6.76P–O(e)(2) would specify “Priority 2—Display Orders.” This proposed priority category would replace the “Display Order Process,” which is described above. As proposed, non-marketable Limit Orders or quotes with a displayed working price would have second priority. For an order or quote that has a display price that differs from the working price of the order or quote, the order or quote would be ranked Priority 3—Non-Display Orders at the working price.⁴¹ This proposed rule is consistent with current functionality. For example, as described above, currently, the display portion of a Reserve Order is subject to the Display Order Process and the reserve portion is subject to the Working Order Process. The proposed level of detail and priority categorization would be new for options trading and the Exchange believes that it would add transparency and specificity to Exchange rules. In addition, this priority category operates the same as how Priority 2 -Display Orders function on the Exchange’s cash equity market, as described in Rule 7.36–E(e)(2), with a difference for the proposed rule to reflect options trading by including reference to quotes.

- Proposed Rule 6.76P–O(e)(3) would specify “Priority 3—Non-Display Orders.” This priority category would be used in Pillar rules instead of reference to the “Working Order Process,” which is described above. As proposed, non-marketable Limit Orders or quotes for which the working price is not displayed, including the reserve interest of Reserve Orders, would have third priority. This proposed rule is consistent with current functionality. The proposed level of detail and priority categorization would be new for options trading and the Exchange believes that it would add transparency and specificity to Exchange rules. In addition, this priority category operates the same as how Priority 3—Non-Display Orders function on the Exchange’s cash equity market, as described in Rule 7.36–E(e)(3), with a difference for the proposed rule to reflect options trading by including reference to quotes.

Proposed Rule 6.76P–O(f) would set forth that at each price level within each priority category, orders and quotes would be ranked based on time priority. This proposed rule is consistent with current Rule 6.76–O(a), which provides, in relevant part, that “within each price level, all bids and offers shall

⁴¹ See, e.g., *infra*, discussion regarding proposed Non-Routable Limit Order per Rule 6.62P–O(e)(1).

be organized by the time of entry.” The proposed changes set forth below are consistent with current functionality and would add detail not included in existing option rules. In addition, the proposed changes use terminology based on Rule 7.36–E(f)(1) and (3), with differences to reference options terminology of “orders and quotes” rather than just “orders” and to the “Consolidated Book” rather than the “NYSE Arca Book.”

- Proposed Rule 6.76P–O(f)(1) would provide that an order or quote is assigned a working time when it is first added to the Consolidated Book based on the time such order or quote is received by the Exchange. This proposed process of assigning a working time to orders is current functionality and is substantively the same as current references to the “time of original order entry” found in several places in Rule 6.76–O. This proposed rule uses Pillar terminology that is substantially the same as in Rule 7.36–E(f)(1). To provide transparency in Exchange rules, the Exchange further proposes to include in proposed Rule 6.76P–O(f) how the working time would be determined for orders that are routed, which is consistent with current options trading functionality. As proposed:

- Proposed Rule 6.76P–O(f)(1)(A) would specify that an order that is fully routed to an Away Market on arrival, per proposed Rule 6.76AP–O(b)(1), would not be assigned a working time unless and until any unexecuted portion of the order returns to the Consolidated Book. The Exchange notes that this is the current process for assigning a working time to an order (although this detail would be new to option trading rules) and uses Pillar terminology that is substantially the same as in Rule 7.36–E(f)(1)(A), with a difference that the proposed rule includes reference to the “Consolidated Book” rather than the “NYSE Arca Book.” This proposed rule is also consistent with current Rule 6.76A–O(c)(2)(C), which provides that when an order or portion of an order has been routed away and is not executed either in whole or in part at the other Market Center, it will be ranked and displayed in the OX Book in accordance with the terms of the order.

- Proposed Rule 6.76P–O(f)(1)(B) would specify that for an order that, on arrival, is partially routed to an Away Market, the portion that is not routed would be assigned a working time. If any unexecuted portion of the order returns to the Consolidated Book and joins any remaining resting portion of the original order, the returned portion of the order would be assigned the same working time as the resting portion of

the order. If the resting portion of the original order has already executed and any unexecuted portion of the order returns to the Consolidated Book, the returned portion of the order would be assigned a new working time. This process for assigning a working time to partially routed orders is the same as currently used by the Exchange (although this detail would be new to option trading rules) and uses Pillar terminology that is substantially the same as in Rule 7.36–E(f)(1)(B)), with a difference that the proposed rule would reference the “Consolidated Book” rather than the “NYSE Arca Book.”

- Proposed Rule 6.76P–O(f)(2) would provide that an order or quote would be assigned a new working time if: (A) The display price of an order or quote changes, even if the working price does not change, or (B) the working price of an order or quote changes, unless the working price is adjusted to be the same as the display price of an order or quote. This proposed text would be new and is different from how the Exchange adjusts the working time for cash equities trading when the working price of an order is updated to be the same as the display price.⁴² The Exchange believes that for its options market, adjusting the working time any time the display price of an order changes, would respect the priority of orders that were previously displayed at the price to which the display price is changing. In addition, the Exchange believes it is appropriate to adjust the working time of an order any time its working price changes, unless the display price does not change. This proposed order handling in Exchange rules is consistent with the rules of other options exchanges.⁴³

- Proposed Rule 6.76P–O(f)(3) would provide that an order or quote would be assigned a new working time if the size of an order or quote increases and that an order or quote retains its working time if the size of the order or quote is decreased. This proposed detail about the process for assigning a new working time when the size of an order changes is not currently described in the Exchange’s option rules but is

⁴² Currently, for cash equity trading, Rule 7.36–E(f)(2) provides that, “[a]n order is assigned a new working time any time the working price of an order changes.” The Exchange plans to propose changes to this cash equity rule to align with that being proposed for its options market at a later date.

⁴³ See, e.g., Cboe BZX (“BZX”) Rule 11.9(g)(1)(B) (providing that, for orders subject to “display price sliding,” BZX “will re-rank an order at the same price as the displayed price in the event such order’s displayed price is locked or crossed by a Protected Quotation of an external market” and that “[s]uch event will not result in a change in priority for the order at its displayed price”).

consistent with existing functionality and uses Pillar terminology. This provision is substantively identical to Rule 7.36–E(f)(3), with a difference to reference “an orders or quotes” as opposed to solely “an order.”

Proposed Rule 6.76P–O(g) would specify that the Exchange would apply ranking restrictions applicable to specified order or modifier instructions. These order and modifier instructions would be identified in proposed new Rule 6.62P–O, described below. Proposed Rule 6.76P–O(g) uses Pillar terminology substantially the same as is used in Rule 7.36–E(g). Current Rule 6.76–O(a)(2)(C)–(E) discusses ranking of certain order types with contingencies in the Working Order Process. The Exchange proposes that for Pillar, ranking details regarding orders with contingencies would be described in proposed Rule 6.62P–O(d). Accordingly, the Exchange does not propose to include the detail described in Rule 6.76–O(a)(2)(C)–(E) in proposed Rule 6.76P–O.

Finally, proposed Rule 6.76P–O(h) would be applicable to “Orders Executed Manually” and would contain the same text as set forth in Rule 6.76–O(d) without any substantive differences except for the non-substantive change of capitalizing the defined term Trading Crowd (per proposed Rule 1.1), removing the superfluous clause “in addition,” and updating the cross-reference to reflect the new Pillar rule.⁴⁴

In connection with proposed Rule 6.76P–O, the Exchange proposes to add the following preamble to Rule 6.76–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.76–O would not be applicable to trading on Pillar.

Proposed Rule 6.76AP–O: Order Execution and Routing

Current Rule 6.76A–O, titled “Order Execution—OX,” governs order execution and routing at the Exchange. The Exchange proposes that Rule 6.76AP–O would set forth the order execution and routing rules for options trading on Pillar. The Exchange proposes that the title for new Rule 6.76AP–O would be “Order Execution and Routing” instead of “Order Execution—OX” because the Exchange does not propose to use the term “OX”

⁴⁴ See proposed Rule 6.76P–O(h)(1) (removing “in addition”) (B) (regarding “Trading Crowd”) and (D) (updating the cross-reference to new subparagraph (B) in connection with the Section 11(a)(1)(G) of the Exchange Act and Rule 11a1–1(T) thereunder (“G exemption rule”).

in connection with Pillar. The Exchange believes that because proposed Rule 6.76AP–O, like Rule 6.76A–O, would specify the Exchange’s routing procedures, referencing to “Routing” in the rule’s title would provide additional transparency in Exchange rules regarding what topics would be covered in new Rule 6.76AP–O. This proposed rule is based on Rule 7.37–E, which describes the order execution and routing rules for cash equity securities trading on the Pillar platform, with differences described below to reflect differences for options trading. In addition, throughout proposed Rule 6.76AP–O, the Exchange proposes to use the term “will” instead of “shall,” which is a stylistic preference that would add consistency to Exchange rules.

Proposed Rule 6.76AP–O(a) and its subparagraphs would set forth the Exchange’s order execution process and would cover the same subject as the preamble to Rule 6.76A–O, which provides that like-priced orders and quotes are matched for execution, provided the execution price is equal to or better than the NBBO, unless such order has been routed to an Away Market at the NBBO.⁴⁵ The Exchange proposes a difference from current Rule 6.76A–O(a)–(c) to use Pillar terminology of “Aggressing Order” and “Aggressing Quote”—rather than refer to an “incoming marketable bid or offer,” because (as described above) the proposed terms are more expansive and allow for interest to be (or become) marketable even after arrival (*i.e.*, not limited to “incoming” interest). As proposed, per Rule 6.76AP–O(a), an Aggressing Order or Aggressing Quote would be matched for execution against contra-side orders or quotes in the Consolidated Book according to the price-time priority ranking of the resting interest, subject to specified parameters.

The Exchange does not propose to include in proposed Rule 6.76AP–O text based on current Rule 6.76A–O(a)(1), which describes “Step 1: Display Order Process,” or text based on current Rule 6.76A–O(b), which describes “Step 2: Working Order Process,” because by proposing detailed text in Rule 6.76P–O(c)–(f) regarding how orders and quotes would be ranked on the Exchange, it would be duplicative and unnecessary to describe this process again in proposed Rule 6.76AP–O. Instead, the Exchange believes that cross referencing the price-time priority

ranking of the resting interest, per proposed Rule 6.76P–O, would provide transparency regarding how an Aggressing Order or Aggressing Quote would trade with resting interest. The Exchange notes that it made a similar change for its cash equity platform to eliminate reference to the “Display Order Process” and “Working Order Process” in Rule 7.37–E when it transitioned to Pillar.⁴⁶

Proposed Rule 6.76AP–O(a)(1) would set forth the LMM Guarantee, which is substantively the same as the current LMM Guarantee, as described in Rule 6.76A–O(a)(1)(A)–(D). Rule 6.76A–O(a)(1)(A) provides, in relevant part, that an LMM or Directed Order Market Maker (“DOMM”) that is quoting at the NBBO may be entitled to an allocation guarantee of the greater of: An amount equal to 40% of the incoming bid or offer up to the LMM’s or DOMM’s disseminated quote size; or the LMM’s or DOMM’s share in the order of ranking. However, current Rule 6.76A–O(a)(1)(A)(ii) provides that if there are Customer orders ranked ahead of the LMM (or DOMM, as applicable), or if there is no LMM (or DOMM) quoting at the NBBO, the incoming bid or offer will be matched against orders and quotes in the Display Process strictly in the order of their ranking. The Exchange proposes a substantive difference because on Pillar, the Exchange would no longer support DOMMs or Directed Orders. Accordingly, rule text relating to DOMMs or Directed Orders will not be included in proposed Rule 6.76AP–O.⁴⁷

Proposed Rule 6.76AP–O(a)(1) would provide that an LMM would be entitled to an allocation guarantee when the execution price is equal to the NBB (NBO) and there is no displayed Customer interest in time priority at the NBBO in the Consolidated Book. In such cases, the Aggressing Order or Aggressing Quote would be matched against the quote of the LMM for an amount equal to 40% of the Aggressing Order or Aggressing Quote, up to the size of the LMM’s quote (the “LMM Guarantee”). With respect to how the LMM Guarantee would function on Pillar, the Exchange does not propose any substantive differences from current Rule 6.76A–O(a)(1), except as noted above to exclude reference to Directed Orders or DOMMs.

Proposed Rule 6.76AP–O(a)(1)(A) would provide that if an LMM has more than one quote at a price, the LMM

Guarantee would be applied only to the first LMM quote in time priority, which text would add granularity and transparency to Exchange rules. This text would be new and reflects that on Pillar, the Exchange would permit multiple quotes from the same LMM at the same price and that only the first quote in time priority would be eligible for the LMM Guarantee.

Proposed Rule 6.76AP–O(a)(1)(B), which is substantively identical to current Rule 6.76A–O(a)(1)(B), would provide that if an LMM is entitled to an LMM Guarantee (pursuant to proposed paragraph (a)(1)) and the Aggressing Order or Aggressing Quote had an original size of five (5) contracts or fewer, then such order or quote would be matched against the quote of the LMM for an amount equal to 100%, up to the size of the LMM’s quote. The Exchange also proposes to add Commentary .01 to the proposed rule (which is substantively identical to Commentary .02 of current Rule 6.76A–O) to make clear that on a quarterly basis, the Exchange would evaluate what percentage of the volume executed on the Exchange comprised of orders for five (5) contracts or fewer that was allocated to LMMs and would reduce the size of the orders included in this provision if such percentage is over 40%.⁴⁸

Proposed Rule 6.76AP–O(a)(1)(C) would specify that if the result of applying the LMM Guarantee is a fractional allocation of contracts, the LMM Guarantee would be rounded down to the nearest contract and if the result of applying the LMM Guarantee results in less than one contract, the LMM Guarantee would be equal to one contract. The Exchange believes that including this additional detail (which is based on current functionality) in the proposed rule would add transparency to Exchange rules.

Finally, the Exchange proposes Rule 6.76AP–O(a)(1)(D), which would provide that after applying any LMM Guarantee, the Aggressing Order or Aggressing Quote would be allocated pursuant to proposed paragraph (a) of this Rule, *i.e.*, that such orders or quotes would be matched for execution against contra-side interest resting in the Consolidated Book according to price-time priority. This proposed text is substantively identical to Rule 6.76A–O(a)(1)(C) and uses Pillar terminology, and eliminates the now obsolete

⁴⁵ Rule 6.76A–O(a)–(c) sets forth a three-step process—the Display Order Process, the Working Order Process, and Routing Away, Steps 1–3, respectively—governing the handling of incoming marketable bids and offers.

⁴⁶ See NYSE Arca Equities Pillar Notice, *supra* note 12 at 28728–29.

⁴⁷ The Exchange proposes to add a preamble to Rule 6.88–O (Directed Orders) to provide that the Rule would not be applicable to trading on Pillar.

⁴⁸ See proposed Rule 6.76AP–O, Commentary .01, which will not include cross-reference that appears in the current rule Commentary .02 to Rule 6.76A–O because the Exchange determined such cross-reference was superfluous and opted to remove excess verbiage.

reference to DOMMs, Directed Orders, and the Display Order Process.

Consistent with the Exchange's proposed approach to new Rule 6.76P-O, proposed Rule 6.76AP-O would not include references to specific order types and instead would state the Exchange's general order execution methodology. Any exceptions to such general requirements would be set forth in connection with specific order or modifier definitions in proposed Rule 6.62P-O, described below.

Proposed Rule 6.76AP-O(b) would set forth the Exchange's routing process and is intended to address the same subject as Rule 6.76A-O(c), which is currently referred to as "Step 3: Routing Away" in order processing, without any substantive differences. Under current Rule 6.76A-O(c), the Exchange will route to another Market Center any unexecuted portion of an order that is eligible to route.⁴⁹ Proposed Rule 6.76AP-O(b) would provide that, absent an instruction not to route, the Exchange would route marketable orders to Away Market(s) after such orders are matched for execution with any contra-side interest in the Consolidated Book in accordance with proposed paragraph (a) of this Rule regarding Order Execution. Proposed Rule 6.76AP-O(b) also uses the same Pillar terminology that is used in current Rule 7.37-E(b), which governs the Exchange's routing process on the Exchange's cash equity platform, with differences to use option trading terminology such as "Consolidated Book."

The proposed rule would then set forth additional details regarding routing that are consistent with current routing functionality, but are not described in current rules:

- Proposed Rule 6.76AP-O(b)(1) would provide that an order that cannot meet the pricing parameters of proposed Rule 6.76AP-O(a) may be routed to Away Market(s) before being matched for execution against contra-side interest in the Consolidated Book. The Exchange believes that this proposed rule text, which is consistent with current functionality, provides transparency that an order may be routed before being matched for execution, for example, to prevent locking or crossing or trading through the NBBO. This rule uses Pillar

⁴⁹ Under the current rule, each eligible order is routed "as limit order equal to the price and up to the size of the quote published by the Market Center(s)" or, if "a marketable Reserve Order, the Exchange may route such order serially as component orders, such that each component corresponds to the displayed size." See Rule 6.76AP-O(c)(1)(A), (B). In the proposed Pillar rule, the Exchange proposes to use the term "Away Market" instead of "Market Center."

terminology that is substantially the same as in Rule 7.37-E(b)(1), with a difference to reference the "Consolidated Book" rather than the "NYSE Arca Book."

- Proposed Rule 6.76AP-O(b)(2) would provide that an order with an instruction not to route would be processed as provided for in proposed Rule 6.62P-O.⁵⁰ As described in greater detail below, the Exchange proposes to describe how orders and quotes with an instruction not to route would be processed in proposed Rule 6.62P-O(e).

- Proposed Rule 6.76AP-O(b)(3) would provide that any order or portion thereof that has been routed would not be eligible to trade on the Consolidated Book, unless all or a portion of the order returns unexecuted. This routing methodology is current functionality and covers that same subject as current Rule 6.76A-O(c)(2) with no substantive differences and is based in part on Pillar terminology used in Rule 7.37-E(b)(6). Similar to Rule 6.76A-O(c)(2)(A), which provides that an order routed to an Away Market is subject to the trading rules of that market and, while so routed, has no standing relative to other orders on the Exchange in the OX Book, the Exchange proposes that Rule 6.76AP-O(b)(3) would state that once routed, an order would not be eligible to trade on the Consolidated Book. The Exchange does not believe it is necessary to include the text that once routed an order would be subject to the routing destination's trading rules, as such detail is obvious and unnecessary. In addition, because, as discussed above, the working time assigned to orders that are routed is being proposed to be addressed in new Rule 6.76P-O(f)(1)(A) and (B), the Exchange believes it would be unnecessary to restate this information in new Rule 6.76AP-O.

- Proposed Rule 6.76AP-O(b)(4) would provide that requests to cancel an order that has been routed in whole or part would not be processed unless and until all or a portion of the order returns unexecuted. This proposed rule uses Pillar terminology and operates substantively the same as Rule 7.37-E(b)(7)(A). This rule represents current functionality and is based on Rule 6.76A-O(c)(2)(B), except that, unlike the current rule, the proposed rule does not state that such orders (while still routed away) are subject to the applicable trading rules of the market to which such order was routed.

⁵⁰ See, e.g., *infra*, discussion regarding proposed Rule 6.62P-O(e), Orders with Instructions Not to Route.

- Finally, proposed Rule 6.76AP-O(c) would provide that after trading with eligible contra-side interest on the Consolidated Book and/or returning unexecuted after routing to Away Market(s), any unexecuted non-marketable portion of an order would be ranked consistent with new Rule 6.76P-O. This rule represents current functionality as set forth in Rule 6.76A-O generally and paragraph (c)(2)(C) as it pertains to orders that were routed away and then returned unexecuted in whole or part to the Exchange without any substantive differences. This proposed rule uses Pillar terminology and operates substantively the same as Rule 7.37-E(c).

The Exchange believes that the specific routing methodologies for an order type or modifier should be included with how the order type is defined, which will be described in proposed Rule 6.62P-O. Accordingly, the Exchange does not believe it needs to specify in proposed Rule 6.76AP-O whether an order is eligible to route, and if so, whether there are any specific routing instructions applicable to the order and therefore will not be carrying over such specifics that are currently included in Rule 6.76A-O.

In connection with proposed Rule 6.76AP-O, the Exchange proposes to add the following preamble to Rule 6.76A-O: "This Rule is not applicable to trading on Pillar." This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.76A-O would not be applicable to trading on Pillar.

Proposed Rule 6.62P-O: Orders and Modifiers

Current Rule 6.62-O (Certain Types of Orders Defined) defines the order types that are currently available for options trading both on the OX system and for open outcry trading on the Exchange. The Exchange proposes that new Rule 6.62P-O would set forth the order types and modifiers that would be available for options trading both on Pillar (*i.e.*, electronic order entry) and in open outcry trading. The Exchange proposes to specify that Rule 6.62-O would not be applicable to trading on Pillar.

Because the Exchange proposes to use for options trading the Pillar technology that is currently used for cash equity trading, the Exchange has identified opportunities to offer additional order and modifier functionality for options trading that is based on existing functionality on cash equity trading but has not previously been available for options trading. In addition, certain order types and modifiers that would be available for options trading on Pillar

would be based on, or similar to, order types and modifiers available on the Exchange's cash equity market. Because there would be similar orders and modifiers on both the Exchange's cash equity and options markets using similar terminology, the Exchange proposes to structure proposed Rule 6.62P-O based on Rule 7.31-E and use similar terminology. The Exchange also proposes to title proposed Rule 6.62P-O as "Orders and Modifiers," which is the title of Rule 7.31-E.

Primary Order Types. Proposed Rule 6.62P-O(a) would specify the Exchange's primary order types, which would be Market Orders and Limit Orders, and is based on Rule 7.31-E(a), which sets forth the Exchange's cash equity primary order types. Similar to Rule 7.31-E(a), proposed Rule 6.62P-O(a) would also set forth the Exchange's proposed Limit Order Price Protection functionality and Trading Collars.

Market Orders. Proposed Rule 6.62P-O(a)(1) would define a Market Order as an unpriced order message to buy or sell a stated number of option contracts at the best price obtainable, subject to the Trading Collar assigned to the order, and would further specify that unexecuted Market Orders may be designated Day or GTC, which represents current functionality, and that unexecuted Market Orders would be ranked Priority 1—Market Orders.⁵¹ This proposed rule text uses Pillar terminology similar to Rule 7.31-E(a)(1) to describe Market Orders for options trading, with differences to reflect options trading functionality. For example, proposed Rule 6.62P-O(a)(1) would specify the ability to designate a Market Order as GTC, which is current options trading functionality that would continue on Pillar (but which modifier is not available on the Exchange's cash equity platform).⁵² Similarly, the

⁵¹ Market Orders are currently defined in Rule 6.62-O(a) as follows: "A Market Order is an order to buy or sell a stated number of option contracts and is to be executed at the best price obtainable when the order reaches the Exchange. Market Orders entered before the opening of trading will be eligible for trading during the Opening Auction Process. The system will reject a Market Order entered during Core Trading Hours if at the time the order is received there is not an NBB and an NBO ("collectively NBBO") for that series as disseminated by OPRA. If the Exchange receives a Market Order to buy (sell) and there is an NBB (NBO) but no NBO (NBB) as disseminated by OPRA at the time the order is received, the order will be processed pursuant to Rule 6.60-O(a)—Trade Collar Protection."

⁵² The ability for a Market Order to be designated Day or GTC is based on current Rules 6.62-O(m) (describing a "Day Order") and 6.62-O(n) (describing a "Good-til-Cancelled Order" or "GTC Order") and Commentary .01 to Rule 6.62-O, which requires all orders to be either "day," "immediate or cancel," or "good 'til cancelled." As described

Exchange proposes to reference that trading of a Market Order would be subject to the Trading Collar assigned to the order, which is similar to the third paragraph of the current definition of Market Order in Rule 6.62-O(a). As described in greater detail below, the Exchange proposes changes to its Trading Collar functionality on Pillar.

Proposed Rule 6.62P-O(a)(1) would further provide that for purposes of processing Market Orders, the Exchange would not use an adjusted NBBO.⁵³ On the Exchange's cash equity market, the Exchange does not use an adjusted NBBO when processing Market Orders. The Exchange proposes to similarly not use an adjusted NBBO when processing Market Orders on its options market, which would be new for options trading. The Exchange believes that because Market Orders trade immediately on arrival, using an unadjusted NBBO would provide a price protection mechanism by using a more conservative view of the NBBO.

Proposed Rule 6.62P-O(a)(1)(A) would provide that a Market Order that arrives during continuous trading would be rejected, or that was routed, returns unexecuted, and has no resting quantity to join would be cancelled if it fails the validations specified in proposed Rule 6.62P-O(a)(1)(A)(i)—(iv). This proposed rule is based in part on Rule 6.62-O(a), which specifies that a Market Order will be rejected during Core Trading Hours if, when received, there is no NBBO for the applicable option series as disseminated by OPRA, with differences to use Pillar terminology and to expand the circumstances when a Market Order would be rejected beyond the absence of an NBBO. As proposed, a Market Order would be rejected (or cancelled if routed first) if:⁵⁴

in more detail below, on Pillar, the time-in-force designation, e.g., Day or GTC, would be a modifier that can be added to an order type and would not be described in the rules as a separate order type. Similar to Rule 7.31-E, the Exchange would specify which time-in-force designations are available for each order type.

⁵³ See discussion *supra*, regarding the proposed Rule 1.1 definition of "NBBO" and that when using an unadjusted NBBO, the NBBO would not be adjusted based on information about orders the Exchange sends to Away Markets, execution reports received from those Away Markets, and certain orders received by the Exchange.

⁵⁴ The Exchange will also reject a Market Order if it is entered when the underlying NMS stock is either in a Limit State or a Straddle State, which is current functionality. See Rule 6.65A-O(a)(1). The Exchange proposes a non-substantive amendment to Rule 6.65A-O(a)(1) to add a cross reference to proposed Rule 6.62P-O(a)(1). The Exchange also proposes to amend the second sentence of Rule 6.65A-O(a)(1) to remove references to trading collars, and instead specify that the Exchange would cancel any resting Market Orders if the underlying NMS stock enters a Limit State or a Straddle State and would notify OTP

- There is no NBO (proposed Rule 6.62P-O(a)(1)(A)(i)). This criterion is similar to the current rule, which provides that a Market Order will be rejected if there is no NBO. The Exchange believes that in the absence of an NBO, Market Orders should not trade as there is no market for the option.

- There is no NBB and the NBO is higher than \$0.50 (for sell Market Orders only). The Exchange further proposes that if there is no NBB and the NBO is \$0.50 or below, a Market Order to sell would not be rejected and would have a working price and display price one MPV above zero and would not be subject to a Trading Collar (proposed Rule 6.62P-O(a)(1)(A)(ii)). The Exchange believes that if there is no NBB, but an NBO \$0.50 or below, the Exchange would be able to price that Market Order to sell at one MPV above zero. The proposed rule would further provide that a Market Order to sell would be cancelled if it was assigned a Trading Collar, routed, and when it returns unexecuted, it has no resting portion to join and there is no NBB, regardless of the price of the NBO. Accordingly, in this scenario, if there is no NBB and there is an NBO that is \$0.50 or below, the returned, unexecuted Market Order would be cancelled rather than displayed at one MPV above zero. The functionality described in this proposed rule would be new and is designed to provide an opportunity for an arriving sell Market Order (that is not first routed) to trade when the NBO is below \$0.50.

- There are no contra-side Market Maker quotes on the Exchange or contra-side Away Market NBBO, provided that a Market Order to sell would be accepted as provided for in proposed Rule 6.62P-O(a)(1)(A)(iii) (proposed Rule 6.62P-O(a)(1)(A)(iii)). This functionality would be new and is designed to prevent a Market Order from trading at prices that may not be current for that series in the absence of Market Maker quotations or an Away Market NBBO.

- The NBBO is not locked or crossed and the spread is equal to or greater than a minimum amount based on the midpoint of the NBBO (proposed Rule 6.62P-O(a)(1)(A)(iv)). The proposed "wide-spread" parameter for purposes of determining whether to reject a Market Order is similar to the wide-spread parameter applied when determining whether a trade is a Catastrophic Error, as set forth in Rule

Holders of the reason for such cancellation. This proposed change would describe both how Market Orders function today on the OX system and how they would be processed on Pillar.

6.87–O(b)(3), with two differences. First, as shown below, the lowest bucket would be \$0.00 up to and including \$2.00, instead of \$0.00 to \$1.99, which means the \$2.00 price point would be included in this bucket. The Exchange proposes this difference because it would simplify the application to have the break points after whole dollar price points. Second, the wide-spread calculation would be based off of the midpoint of the NBBO, rather than off of the bid price, as follows:

The midpoint of the NBBO	Spread parameter
\$0.00 to \$2.00	\$0.75
Above \$2.00 to and including \$5.00	1.25
Above \$5.00 to and including \$10.00	1.50
Above \$10.00 to and including \$20.00	2.50
Above \$20.00 to and including \$50.00	3.00
Above \$50.00 to and including \$100.00	4.50
Above \$100.00	6.00

The Exchange notes that this proposed protection for Market Orders is a new risk control designed to protect against erroneous executions and use of the midpoint of the NBBO as a basis for a price protection mechanism is consistent with similar functionality on other options markets.⁵⁵

Proposed Rule 6.62P–O(a)(1)(B) would provide that an Aggressing Market Order to buy (sell) would trade with all orders or quotes to sell (buy) on the Consolidated Book priced at or below (above) the Trading Collar before routing to Away Market(s) at each price.⁵⁶ Proposed Rule 6.62P–O(a)(1)(B) would further provide that after trading or routing, or both, a Market Order would be displayed at the Trading Collar, subject to proposed Rule 6.62P–O(a)(1)(C), which is consistent with current functionality that Market Orders would be displayed at a Trading Collar, per Rule 6.60–O(a)(5).

Proposed Rule 6.62P–O(a)(1)(C) would provide that a Market Order would be cancelled before being displayed if there are no remaining contra-side Market Maker quotes on the Exchange or contra-side Away Market NBBO. Proposed Rule 6.62P–O(a)(1)(D)

would provide that a Market Order would be cancelled after being displayed at its Trading Collar if there ceases to be a contra-side NBBO. These proposed cancellation events are similar to functionality described in Rule 6.60–O(a)(4)(E), which provides that “[t]he Exchange will cancel a Market Order, or the balance thereof, that has been collared pursuant to paragraph (a)(1)(A) or (B) [of that Rule] above, if after exhausting trading opportunities within the Collar Range, the Exchange determines there are no quotes on the Exchange and/or no interest on another market in the affected option series.” As proposed, in Pillar, the Exchange would cancel a Market Order in similar circumstances, with proposed modifications that a Market Order would be cancelled only if there are no remaining contra-side Market Maker quotes on the Exchange or if there is no contra-side Away Market NBBO. The Exchange believes that this proposed change from the current rule would provide that a Market Order would be cancelled when there is no contra-side interest against which to determine the price at which such order could trade.

Finally, proposed Rule 6.62P–O(a)(1)(E) would provide that a resting, displayed Market Order that is locked or crossed by an Away Market would be routed to that Away Market. Because Market Orders are intended to trade at the best price obtainable, the Exchange proposes to route displayed Market Orders if they are locked or crossed by an Away Market.⁵⁷ This proposed Rule is based on current functionality, which is not described in current rule. Therefore, the proposed rule is designed to promote clarity and transparency in Exchange rules.

Limit Orders. Proposed Rule 6.62P–O(a)(2) would define a Limit Order as an order message to buy or sell a stated number of option contracts at a specified price or better, subject to Limit Order Price Protection and the Trading Collar assigned to the order, and that a Limit Order may be designated Day, IOC, or GTC. In addition, unless otherwise specified, the working price and the display price of a Limit Order would be equal to the limit price of the order, it is eligible to be routed, and it would be ranked under the proposed category of “Priority 2—Display Orders.” This proposed rule text uses

Pillar terminology that is based in part on Rule 7.31–E(a)(2). The ability for a Limit Order to be designated IOC, Day, or GTC is based on current Rules 6.62–O(k), (m) and (n), respectively, and therefore would differ from the cash equity rules because (unlike on the cash equity platform) a Limit Order could be designated GTC, but is consistent with current options trading functionality. In addition, unlike cash equity trading, but consistent with current options trading functionality, Limit Orders would be subject to trading collars. As described in more detail below, on Pillar, trading collars will differ from both current options trading collar functionality and trading collar functionality available on the Exchange’s cash equity platform (which is available only for Market Orders). Proposed Rule 6.62P–O(a)(2)(A) would provide that a marketable Limit Order to buy (sell) received by the Exchange would trade with all orders and quotes to sell (buy) on the Consolidated Book priced at or below (above) the NBO (NBB) before routing to an Away Market NBO (NBB) and may route to prices higher (lower) than the NBO (NBB) only after trading with orders and quotes to sell (buy) on the Consolidated Book at each price point, and once no longer marketable, the Limit Order would be ranked and displayed on the Consolidated Book. This proposed rule text is based on Rule 6.62–O(b), which provides that a “‘marketable’ limit order is a Limit Order to buy (sell) at or above (below) the NBBO.” The proposed rule text is more specific and uses the same Pillar terminology used to describe Limit Orders in Rule 7.31–E(a)(2)(A) for cash equity trading. In addition, proposed Rule 6.62P–O(a)(2)(A) would use terminology specific to options trading (*i.e.*, the proposed rule refers to the Consolidated Book rather than the NYSE Arca Book as well as to the NBBO as opposed to the PBBO).

Limit Order Price Protection. The Exchange proposes to describe its proposed Limit Order Price Protection functionality in proposed Rule 6.62P–O(a)(3). On the OX system, the concept of “Limit Order Price Protection” for orders is set forth in Rule 6.60–O(b) and is called the “Limit Order Filter.” For quotes, price protection filters are described in Rule 6.61–O. The proposed “Limit Order Price Protection” on Pillar would be applicable to both Limit Orders and quotes and, at a high level, would work similarly to how the current price protection mechanisms function on the OX system because a Limit Order or quote would be rejected if it is priced at a specified threshold

⁵⁵ See, e.g., Cboe Rule 5.34(a)(2) (setting forth the “Market Order NBBO Width Protection” wherein Cboe cancels or rejects market orders submitted “when the NBBO width is greater than x% of the midpoint of the NBBO,” subject to minimum and maximum dollar values determined by Cboe).

⁵⁶ The Exchange has defined an Aggressing Order in proposed Rule 6.76P–O(a)(5). An Aggressing Market Order is a Market Order that is an Aggressing Order.

⁵⁷ As described above for proposed Rule 6.76P–O(b)(3), displayed interest other than displayed Market Orders would stand their ground if locked or crossed by an Away Market. The Exchange would provide an option for Limit Orders to instead be routed, see discussion *infra*, regarding proposed Rule 6.62P–O(i)(1) and the proposed Proactive if Locked/Crossed Modifier.

away from the contra-side NBB or NBO.⁵⁸ The Exchange proposes to enhance the functionality for options trading on Pillar by using new thresholds and reference prices (as discussed further below) that would be applicable to both orders and quotes. The concept of a “Reference Price” as used in connection with risk controls would be new for options but consistent with Pillar terminology for the Exchange’s cash equity market as well as how this term is used on other option exchanges.⁵⁹ Thus, this term is not new or novel.

Proposed Rule 6.62P–O(a)(3)(A) would provide that each trading day, a Limit Order or quote to buy (sell) would be rejected or cancelled (if resting) if it is priced at a “Specified Threshold,” described below, equal to or above (below) the Reference Price, rounded down to the nearest price within the MPV for the Series (“Limit Order Price Protection”). In other words, a Limit Order designated GTC would be re-evaluated for Limit Order Price Protection on each day that it is eligible to trade and would be cancelled if the limit price is through the Specified Threshold. In addition, the proposed rounding down is consistent with current functionality, is standard on Pillar for price protection mechanisms, and is based on how Limit Order Price Protection is calculated on the Exchange’s cash equity market if it is not within the MPV for the security, as described in the last sentence of Rule 7.31–E(a)(2)(B). The proposed text would therefore promote granularity in Exchange rules. The proposed rule would further provide that Cross Orders and Limit-on-Open (“LOO”) Orders (described below) as well as orders represented in open outcry, would not be subject to Limit Order Price Protection and that Limit Order Price

Protection would not be applied to a Limit Order or quote if there is no Reference Price, which is consistent with current functionality.

- Proposed Rule 6.62P–O(a)(3)(A)(i) would provide that a Limit Order or quote that arrives when a series is open would be evaluated for Limit Order Price Protection on arrival.

- Proposed Rule 6.62P–O(a)(3)(A)(ii) would provide that a Limit Order or quote received during a pre-open state would be evaluated for Limit Order Price Protection after an Auction concludes.⁶⁰

- Proposed Rule 6.62P–O(a)(3)(A)(iii) would provide that a Limit Order or quote that was resting on the Consolidated Book before a trading halt would be evaluated for Limit Order Price Protection again after the Trading Halt Auction concludes.

The Exchange believes that these proposed rules would add clarity and transparency to when the Exchange would evaluate a Limit Order or quote for Limit Order Price Protection.

Proposed Rule 6.62P–O(a)(3)(B) would specify that the Reference Price for calculating Limit Order Price Protection for an order or quote to buy (sell) would be the NBO (NBB), provided that, immediately following an Auction, the Reference Price would be the Auction Price, or if none, the upper (lower) Auction Collar price, or, if none, the NBO (NBB). The Exchange believes that adjusting the Reference Price for Limit Order Price Protection immediately following an Auction would ensure that the most up-to-date price would be used to assess whether to cancel a Limit Order that was received during a pre-open state or would be reevaluated after a Trading Halt Auction. The Exchange further proposes that for purposes of calculating Limit Order Price Protection, the Exchange would not use an adjusted NBBO, which use of an unadjusted NBBO is consistent with how Limit Order Price Protection currently functions on the Exchange’s cash equity market, as described in Rule 7.31–E(a)(2)(B).⁶¹ The Exchange believes that using an unadjusted NBBO for risk protection mechanisms is consistent with the goal of such mechanisms to prevent erroneous executions by using a more conservative view of the NBBO.

Proposed Rule 6.62P–O(a)(3)(C) would specify the Specified Threshold and would provide that unless determined otherwise by the Exchange and announced to OTP Holders and OTP Firms by Trader Update, the Specified Threshold applicable to Limit Order Price Protection would be:

Reference price	Specified threshold
\$0.00 to \$1.00	\$0.30
\$1.01 to \$10.00	50%
\$10.01 to \$20.00	40%
\$20.01 to \$50.00	30%
\$50.01 to \$100.00	20%
\$100.01 and higher	10%

The Exchange believes that it would provide a more reasonable and deterministic trading outcome to use a fixed dollar amount (of \$0.30) rather than a percentage calculation when the Reference Price is \$1.00 or less. The Exchange believes that the balance of the proposed thresholds are more granular than those currently specified in Rules 6.60–O(b) (for orders) and 6.61–O(a)(1)(A) and (B) (for quotes) and therefore determining whether to reject a Limit Order or quote will be more tailored to the applicable Reference Price. In addition, consistent with Rules 6.60–O(b) and 6.61–O(a)(1), the Exchange proposes that these thresholds could change, subject to announcing the changes by Trader Update. Providing flexibility in Exchange rules regarding how the Specified Thresholds would be set is consistent with the rules of other options exchanges.⁶²

Trading Collar. Trading Collars on the OX system are currently described in Rule 6.60–O(a). Under the current rules, incoming Market Orders and marketable Limit Orders are limited in having an immediate execution if they would trade at a price greater than one “Trading Collar.” A collared order is displayed at that price and then can be repriced to new collars as the NBBO updates. On Pillar, the Exchange proposes Trading Collar functionality that would be new for Pillar and is not currently available on the Exchange’s cash equity platform.

Unlike current options trading collar functionality, which permits a collared order to be repriced, as proposed, a Market Order or Limit Order would be assigned a single Trading Collar that

⁵⁸ Current Rule 6.60–O(b) provides that unless otherwise determined by the Exchange, the specified threshold percentage for orders is 100% when the contra-side NBB or NBO is priced at or below \$1.00 and 50% when the contra-side NBB or NBO is priced above \$1.00. Current Rule 6.61–O(a)(1)(A) provides that unless otherwise determined by the Exchange, the specified threshold for Market Maker bids is \$1.00 if the contra-side NBO is priced at or below \$1.00 and for Market Maker offers no limit if the NBB is priced at or below \$1.00. Current Rule 6.61–O(a)(1)(B) provides that unless otherwise determined by the Exchange, the specified threshold for Market Maker bids is 50% if the contra-side NBO (NBB) is priced above \$1.00.

⁵⁹ See, e.g., Cboe Rule 5.6(c) (setting forth the “reference price” applicable to orders for which Cboe delta-adjusts the execution price after the market close). As discussed *infra*, the Exchange likewise proposes to use the term Reference Price in connection with Trading Collars (proposed Rule 6.62P–O(a)(4)) and other risk checks (proposed Rule 6.41P–O).

⁶⁰ See discussion *infra*, regarding proposed Rule 6.64P–O(a) and proposed definitions for the terms “Auction,” “Auction Price,” “Auction Collar,” “pre-open state,” and “Trading Halt Auction.”

⁶¹ References to the NBBO, NBB, and NBO in Rule 7.31–E refer to using a determination of the national best bid and offer that has not been adjusted.

⁶² See, e.g., Cboe Rule 5.34(a)(4) (describing the “Drill-Through Protection” and that Cboe “determines the buffer amount on a class and premium basis”); and the Nasdaq Stock Market LLC (“Nasdaq”) Options 3, Section 15(a)(1)(B) (specifying that “Order Price Protection” can be a configurable dollar amount specified by Nasdaq and announced via an Options Trader Alert).

would be applicable to that order until it is fully executed or cancelled (unless the series is halted). The new proposed Trading Collar would function as a ceiling (for buy orders) or floor (for sell orders) of the price at which such order could be traded, displayed, or routed. The Exchange further proposes that when an order is working at its assigned Trading Collar, it would cancel if not executed within a specified time period.

More specifically, proposed Rule 6.62P-O(a)(4) would provide that a Market Order or Limit Order to buy (sell) would not trade or route to an Away Market at a price above (below) the Trading Collar assigned to that order. As further proposed, Auction-Only Orders, Limit Orders designated IOC or FOK, Cross Orders, ISOs, and Market Maker quotes would not be subject to Trading Collars, which interest is excluded under current functionality.⁶³ The proposed rule would explicitly add reference to Cross Orders being excluded from Trading Collars, which would add granularity to the proposed rule. In addition, Trading Collars would not be applicable during Auctions but (as described below) would be calculated after such Auction concludes.

Proposed Rule 6.62P-O(a)(4)(A) would provide that a Trading Collar assigned to an order would be calculated once per trading day and would be updated only if the series is halted. Accordingly, an order designated GTC would receive a new Trading Collar each day, but that Trading Collar would not be updated intraday unless the series is halted. Proposed Rule 6.62P-O(a)(4)(A)(i) would provide that an order that is received during continuous trading would be assigned a Trading Collar before being processed for either trading, repricing, or routing and that an order that is routed on arrival and returned unexecuted would use the Trading Collar previously assigned to it. Proposed Rule 6.62P-O(a)(4)(A)(ii) would provide that an order received during a pre-open state would be assigned a Trading Collar after an Auction concludes. Finally, proposed Rule 6.62P-O(a)(4)(A)(iii) would provide that the Trading Collar for an order resting on the Consolidated Book before a trading halt would be calculated again after the Trading Halt Auction concludes. The Exchange believes that because Trading Collars are intended as a price protection mechanism, updating the Trading Collar

after a series has reopened would allow for the Trading Collar assigned to an order to reflect more updated pricing.

Proposed Rule 6.62P-O(a)(4)(B) would provide that the Reference Price for calculating the Trading Collar for an order to buy (sell) would be the NBO (NBB), which is consistent with how trading collars are currently determined for Limit Orders, with differences to use this Reference Price for all orders and for how the Reference Price would be determined after an Auction.⁶⁴ The Exchange proposes to use the Pillar term "Reference Price" to describe what would be used for Trading Collar calculations.⁶⁵ The proposed rule would further provide that for Auction-eligible orders to buy (sell) that were received during a pre-open state or orders that were re-assigned a Trading Collar after a trading halt, the Reference Price would be the Auction Price or, if none, the upper (lower) Auction Collar price or, if none, the NBO (NBB). For reasons similar to those described above, the Exchange proposes to use a more conservative view of the NBBO for purposes of risk protection mechanisms. Therefore, the Exchange proposes that for purposes of calculating a Trading Collar, the Exchange would not use an adjusted NBBO. Proposed Rule 6.62P-O(a)(4)(B)(i) would further provide that a Trading Collar would not be assigned to a Limit Order if there is no Reference Price at the time of calculation, which is consistent with current functionality and the proposed rule would add granularity to Exchange rules.

Proposed Rule 6.62P-O(a)(4)(C) would describe how the Trading Collar would be calculated and would provide that the Trading Collar for an order to buy (sell) would be a specified amount above (below) the Reference Price, as follows: (1) For orders with a Reference Price of \$1.00 or lower, \$0.25; or (2) for orders with a Reference Price above \$1.00, the lower of \$2.50 or 25%. Trading Collars under the current rule are based on a specified dollar amount (set forth in four tranches).⁶⁶ The Exchange believes the proposed functionality (set forth in two tranches) would tailor the Trading Collar

calculations with either a specified dollar amount or percentage, depending on the Reference Price of the order, while at the same time providing that the thresholds would be within the current parameters for determining whether a trade is an Obvious Error or Catastrophic Error.⁶⁷ Proposed Rule 6.62P-O(a)(4)(C)(i) would further provide that if the calculation of a Trading Collar would not be in the MPV for the series, it would be rounded down to the nearest price within the applicable MPV, which is consistent with current functionality and based on how Trading Collars are calculated on the Exchange's cash equity market, as described in Rule 7.31-E(a)(1)(B). Proposed Rule 6.62P-O(a)(4)(C)(ii) would further provide that for orders to sell, if subtracting the Trading Collar from the Reference Price would result in a negative number, the Trading Collar for Limit Orders would be the limit price and the Trading Collar for Market Orders would be one MPV above zero, which would provide more granularity in Exchange rules and would ensure that there will be a Trading Collar calculated for low-priced orders to sell.

Proposed Rule 6.62P-O(a)(4)(D) would describe how the Trading Collar would be applied and would provide that if an order to buy (sell) would trade or route above (below) the Trading Collar or would have its working price repriced to a Trading Collar that is below (above) its limit price, the order would be added to the Consolidated Book at the Trading Collar for 500 milliseconds and if not traded within that period, would be cancelled. In addition, once the 500-millisecond timer begins for an order, the order would be cancelled at the end of the timer even if it repriced or has been routed to an Away Market during that period, in which case any portion of the order that is returned unexecuted would be cancelled.

The Exchange believes that the proposed Trading Collar functionality is designed to provide a similar type of order protection as is currently available (as described in Rule 6.60-O(a)) because it would limit the price at which a marketable order could be traded, routed, or displayed. The Exchange believes that the proposed differences are designed to simplify the functionality by applying a static ceiling price (for a buy order) or floor price (for a sell order) at which such order could be traded or routed that would be determined at the time of entry (or after

⁶³ See Rule 6.60-O(a)(3) ("Trade Collar Protection does not apply to quotes, IOC Orders, AON Orders, FOK Orders, and NOW Orders.").

⁶⁴ Under current rules, trading collars are calculated based off of the contra-side NBBO. See Rule 6.60-O(a)(1)(A)(ii).

⁶⁵ See discussion regarding Cboe Rule 5.34(a)(4) and Nasdaq Options 3, Section 15(a)(1)(B), *supra* note 62.

⁶⁶ Under the current rule, the Trading Collar for buy (sell) orders is as follows: \$0.25 for each option contract for which the NBB (NBO) is less than \$2.00; \$0.40 where the NBB (NBO) is between \$2.00-\$5.00; \$0.50 where the NBB (NBO) is between \$5.01-\$10.00; \$0.80 where the NBB (NBO) is between \$10.01 but does not exceed-\$20.00; and \$1.00 when the NBB (NBO) is \$20.01 or more.

⁶⁷ See Rules 6.87-O(c)(1) (thresholds for Obvious Errors) and 6.87-O(d)(1) (thresholds for Catastrophic Errors).

a series opens or reopens), and would be applicable to the order until it is traded or cancelled. The Exchange believes that the proposed functionality would provide greater determinism to an OTP Holder or OTP Firm of the Trading Collar that would be applicable to a Market Order or Limit Order and when such order may be cancelled if it reaches its Trading Collar.

Time in Force Modifiers. Proposed Rule 6.62P-O(b) would set forth the time-in-force modifiers that would be available for options trading on Pillar and uses Pillar terminology similar to that used in Rule 7.31-E(b), with differences to offer time-in-force modifiers currently available for options trading that are not available for cash equity trading. The Exchange proposes to offer the same time-in-force modifiers that are currently available for options trading on the Exchange and use Pillar terminology to describe the functionality. As noted above, the Exchange proposes to describe the Time in Force Modifiers in proposed Rule 6.62P-O(b), and then specify for each order type which Time in Force Modifiers would be available for such orders or quotes.

Day Modifier. Proposed Rule 6.62P-O(b)(1) would provide that any order or quote to buy or sell designated Day, if not traded, would expire at the end of the trading day on which it was entered and that a Day Modifier cannot be combined with any other Time in Force Modifier. This proposed rule text uses Pillar terminology based on Rule 7.31-E(b)(1) with one difference to reference “quotes” in addition to orders. This proposed functionality would operate no differently than how a “Day Order,” as described in Rule 6.62-O(m), currently functions.

Immediate-or-Cancel (“IOC”) Modifier. Proposed Rule 6.62P-O(b)(2) would provide that a Limit Order may be designated IOC or Routable IOC, as described in proposed Rules 6.62P-O(b)(2)(A) and (B) and that a Limit Order designated IOC would not be eligible to participate in any Auctions. This proposed rule text is based on the first and third sentences of Rule 7.31-E(b)(2) without any differences and makes explicit current (but not defined) functionality.⁶⁸ The Exchange proposes to use Pillar terminology based on Rule

7.31-E(b)(2) to describe this functionality.

Proposed Rule 6.62P-O(b)(2)(A) would define a “Limit IOC Order” as a Limit Order designated IOC that would be traded in whole or in part on the Exchange as soon as such order is received, and the unexecuted quantity would be cancelled and that a Limit IOC Order does not route. This proposed rule text uses Pillar terminology based on Rule 7.31-E(b)(2)(A) without any substantive differences. The proposed Pillar Limit IOC Order would function the same as an “Immediate-or-Cancel Order (IOC Order),” as currently described in Rule 6.62-O(k), without any differences.

Proposed Rule 6.62P-O(b)(2)(B) would define a “Limit Routable IOC Order” as a Limit Order designated Routable IOC that would be traded in whole or in part on the Exchange as soon as such order is received, and the unexecuted quantity routed to Away Market(s) and that any quantity not immediately traded either on the Exchange or an Away Market would be cancelled. This proposed rule text uses Pillar terminology based on Rule 7.31-E(b)(2)(B) without any substantive differences. The proposed Pillar Limit Routable IOC Order is also based on the “NOW Order,” as currently described in Rule 6.62-O(o) and uses Pillar terminology.

Fill-or-Kill (“FOK”) Modifier: Proposed Rule 6.62P-O(b)(3) would provide that a Limit Order designated FOK would be traded in whole on the Exchange as soon as such order is received, and if not so traded is to be cancelled and that a Limit Order designated FOK does not route and does not participate in any Auctions. The Exchange does not offer the FOK Modifier on its cash equity market, and this proposed rule uses Pillar terminology to offer the same functionality that is currently described in Rule 6.62-O(l) as the “Fill-or-Kill Order (FOK Order)” without any substantive differences.

Good-Til-Cancelled (“GTC”) Modifier. Proposed Rule 6.62P-O(b)(4) would provide that a Limit or Market Order designated GTC remains in force until the order is filled, cancelled, the MPV in the series changes overnight, the option contract expires, or a corporate action results in an adjustment to the terms of the option contract. The Exchange does not offer the GTC Modifier on its cash equity market, and this proposed rule uses Pillar terminology to offer the same functionality that is currently described in Rule 6.62-O(n) as the “Good-Till-Cancelled (GTC Order),” with the

substantive difference that the proposed text makes clear (consistent with current functionality) that such orders may be cancelled if the MPV changes overnight. Otherwise, the proposed Rule describes the same functionality that is currently described in Rule 6.62-O(n) as the “Good-Till-Cancelled (GTC Order).”

Auction-Only Orders. Proposed Rule 6.62P-O(c) would define an “Auction-Only Order” as a Limit Order or Market Order that is to be traded only in an Auction pursuant to Rule 6.64P-O,⁶⁹ which uses Pillar terminology based on Rule 7.31-E(c) in lieu of the current description of an “Opening Only Order” set forth in Rule 6.62-O(r), without any functional differences to how such orders trade on Pillar.⁷⁰ The proposed rule would further provide that an Auction-Only Order would not be accepted when a series is opened for trading (*i.e.*, would be accepted only during a pre-open state, which includes a trading halt) and any portion of an Auction-Only Order that is not traded in a Core Open Auction or Trading Halt Auction would be cancelled. This represents current functionality.⁷¹ The proposed rule is designed to provide clarity and uses Pillar terminology from both the last sentence of Rule 7.31-E(c)(1) and the last sentence of Rule 7.31-E(c)(2) for options trading.

Proposed Rule 6.62P-O(c)(1) would define a “Limit-on-Open Order (‘LOO Order’)” as a Limit Order that is to be traded only in an Auction. This proposed rule uses Pillar terminology based on Rule 7.31-E(c)(1) to describe functionality that would be no different from current functionality, as described in Rule 6.62-O(r).

Proposed Rule 6.62P-O(c)(2) would define a “Market-on-Open Order (‘MOO Order’)” as a Market Order that is to be traded only in an Auction. This proposed rule uses Pillar terminology based on Rule 7.31-E(c)(2) to describe functionality that would be no different from current functionality, as described in Rule 6.62-O(r).

Proposed Rule 6.62P-O(c)(3) would define an “Imbalance Offset Order (‘IO Order’)” The Exchange currently offers an IO Order for participation in Trading

⁶⁹ See discussion *infra*, regarding proposed Rule 6.64P-O and definitions relating to Auctions. As proposed, an “Auction” includes the opening or reopening of a series for trading either on a trade or quote. See proposed Rule 6.64P-O(a)(5).

⁷⁰ Rule 6.62-O(r) defines an “Opening Only Order” as “a Market Order or Limit Order which is to be executed in whole or in part during the opening auction of an options series or not at all. Any portion not so executed is to be treated as cancelled.”

⁷¹ See Rule 6.62-O(r) (providing that any portion of an Opening Only Order “not so executed is to be treated as cancelled.”)

⁶⁸ The proposed rule does not include the second sentence of Rule 7.31-E(b)(2), which provides that the “IOC Modifier will override any posting or routing instructions of orders that include the IOC Modifier,” as this functionality is not applicable to options because an order that is not eligible to include an IOC Modifier would be rejected on Pillar.

Halt Auctions on its cash equity market but does not offer this order type for options trading on the OX system. For cash equity trading, the IO Order is a conditional order type that is eligible to participate in a Trading Halt Auction only if it would offset the imbalance. To provide OTP Holders and OTP Firms with greater flexibility for options trading on Pillar, the Exchange proposes to offer more expansive functionality than is currently available for cash equity trading and to offer the IO Order for both Core Open Auctions and Trading Halt Auctions.

As proposed, the IO Order would function no differently than how an IO Order currently functions on the Exchange's cash equity market (except that it would be eligible to trade in all Auctions). Accordingly, proposed Rule 6.62P-O(c)(3) would define an IO Order as a Limit Order that is to be traded only in an Auction, which is based on Rule 7.31-E(c)(5), with a difference that for options trading, it would also be available for Core Open Auctions.

- Proposed Rule 6.62P-O(c)(3)(A) would provide that an IO Order would participate in an Auction only if: (1) There is an Imbalance in the series on the opposite side of the market from the IO Order after taking into account all other orders and quotes eligible to trade at the Indicative Match Price; and (2) the limit price of the IO Order to buy (sell) would be at or above (below) the Indicative Match Price. This proposed text is based on Rule 7.31-E(c)(5)(B) except that it includes reference to quotes, which are unique to options trading, and does not limit the order type to Trading Halt Auctions.

- Proposed Rule 6.62P-O(c)(3)(B) would provide that the working price of an IO Order to buy (sell) would be adjusted to be equal to the Indicative Match Price, provided that the working price of an IO Order would not be higher (lower) than its limit price. This proposed text is based on Rule 7.31-E(c)(5)(C) without any differences.

Orders with a Conditional or Undisplayed Price and/or Size. Proposed Rule 6.62P-O(d) would set forth the orders with a conditional or undisplayed price and/or size that would be available for options trading on Pillar. On Pillar, the Exchange proposes to offer the same type of orders that are available in the OX system and that are currently described in Rule 6.62-O(d) as a "Contingency Order or Working Order," with changes as described below.

Reserve Order. Reserve Orders are currently defined in Rule 6.62-O(d)(3). The Exchange proposes that for options traded on Pillar, Reserve Orders would

function similarly to how Reserve Orders function on its cash equity market, as described in Rule 7.31-E(d)(1), with differences described below. Accordingly, the Exchange proposes that proposed Rule 6.62P-O(d)(1), which would define Reserve Orders for options trading on Pillar, would use Pillar terminology based on Rule 7.31-E(d)(1), with differences to reflect differences in options and cash equity trading. For example, options trading does not have a concept of "round lot" or "odd lot" trading, and therefore the proposed options trading version of the Rule would not include a description of behavior that correlates to such functionality.

Proposed Rule 6.62P-O(d)(1) would define a Reserve Order as a Limit Order with a quantity of the size displayed and with a reserve quantity of the size ("reserve interest") that is not displayed and that the displayed quantity of a Reserve Order is ranked under the proposed category of "Priority 2—Display Orders" and the reserve interest is ranked under the proposed category of "Priority 3—Non-Display Orders." This proposed rule text is based on Rule 7.31-E(d)(1) without any differences. This proposed rule text is also consistent with Rule 6.76-O(a)(1)(B) and (a)(2), with orders ranked under the proposed category of "Priority 2—Display Orders" functioning the same as orders in the current "Display Order Process" and orders ranked under the proposed category of "Priority 3—Non-Displayed Orders" functioning the same as orders in the current "Working Order Process." Proposed Rule 6.62P-O(d)(1) would further provide that both the display quantity and the reserve interest of an arriving marketable Reserve Order would be eligible to trade with resting interest in the Consolidated Book or route to Away Markets, unless designated as a Non-Routable Limit Order, which is based on the third sentence of Rule 7.31-E(d)(1) with a non-substantive difference to add reference to Non-Routable Limit Order.

Proposed Rule 6.62P-O(d)(1) would further provide that the working price of the reserve interest of a resting Reserve Order to buy (sell) would be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule, provided that it would never be priced higher (lower) than the working price of the display quantity of the Reserve Order. This proposed rule text is based on the last sentence of Rule 7.31-E(d)(1) with one difference to reference that the reserve interest could never have a working price that is more aggressive than the working price of the display

quantity of the Reserve Order, which would be new functionality on Pillar for options trading (and not currently available for cash equity trading) designed to ensure that the reserve interest of a Reserve Order to buy (sell) would never trade at a price higher (lower) than the working price of the display quantity of the Reserve Order.⁷²

- Proposed Rule 6.62P-O(d)(1)(A) would provide that the displayed portion of a Reserve Order would be replenished when the display quantity is decremented to zero and that the replenish quantity would be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity. This proposed rule text is based on Rule 7.31-E(d)(1)(A) with differences to reflect that options are not traded in "round lots" or "odd lots." Accordingly, the Exchange would not replenish a Reserve Order on the options trading platform until the display portion is fully decremented, which is consistent with current functionality as described in Rule 6.76-O(a)(1)(B).

- Proposed Rule 6.62P-O(d)(1)(B) would provide that each time the display quantity of a Reserve Order is replenished from reserve interest, a new working time would be assigned to the replenished quantity, which is consistent with current Rule 6.76-O(a)(1)(B)(ii), which provides that when refreshed, the new display quantity will be ranked at the new time that the displayed portion of the order was refreshed. This proposed rule text is based in part on Rule 7.31-E(d)(1)(B) with differences to reflect that for options traded on Pillar, there would never be more than one display quantity of a Reserve Order, and therefore the Exchange would not have different "child" display quantities of a Reserve Order with different working times, as could occur for a Reserve Order on the Exchange's cash equity trading platform.

- Proposed Rule 6.62P-O(d)(1)(C) would provide that a Reserve Order may be designated as a Non-Routable Limit Order and if so designated, the reserve interest that replenishes the display quantity would be assigned a display

⁷² For example, as described in more detail below, the proposed Non-Routable Limit Order would be eligible to be repriced only once after it is resting in the Consolidated Book (see proposed Rule 6.62P-O(e)(1)). If the display quantity of a Non-Routable Limit Order that is combined with a Reserve Order has already been repriced and is no longer eligible to be repriced, and the Away Market NBBO adjusts, the reserve quantity would not adjust to a price that would be more aggressive than the working price of the display quantity of the order. This functionality is not currently available on the Exchange's cash equity market.

price and working price consistent with the instructions for the order. This proposed rule text is based on Rule 7.31–E(d)(1)(B)(ii) without any substantive differences. The Exchange believes that the proposed rule would promote transparency and granularity in Exchange rules.

- Proposed Rule 6.62P–O(d)(1)(D) would provide that a routable Reserve Order would be evaluated for routing both on arrival and each time the display quantity is replenished, which is consistent with Rule 6.76A–O(c)(1)(B), which provides that a Reserve Order may be routed serially as component orders. Proposed Rule 6.62P–O(d)(1)(D)(i) would provide that if routing is required, the Exchange would route from reserve interest before publishing the display quantity. And proposed Rule 6.62P–O(d)(1)(D)(ii) would provide that any quantity of a Reserve Order that is returned unexecuted would join the working time of the reserve interest and that if there is no reserve interest to join, the returned quantity would be assigned a new working time. This proposed rule text is based on Rule 7.31–E(d)(1)(D) and subparagraphs (i) and (ii) with differences to reflect that there is no concept of round lots or multiple child display orders for options trading. The Exchange believes that the proposed rule would promote transparency and granularity in Exchange rules.

- Proposed Rule 6.62P–O(d)(1)(E) would provide that a request to reduce the size of a Reserve Order would cancel the reserve interest before cancelling the display quantity. This proposed rule text is based on Rule 7.31–E(d)(1)(E) with differences only to reflect that there would not be more than one child display order for options trading of Reserve Orders on Pillar. The Exchange believes that the proposed rule would promote transparency and granularity in Exchange rules.

- Proposed Rule 6.62P–O(d)(1)(F) would provide that a Reserve Order may be designated Day or GTC, but it may not be designated as an ALO Order. This proposed rule text is based in part on Rule 7.31–E(d)(1)(C), with differences to reflect that the GTC Modifier would be available for Reserve Orders trading on the Pillar options trading platform (consistent with current functionality) and that Primary Pegged Orders would not be available for options traded on Pillar (also consistent with current functionality). The Exchange believes that the proposed rule would promote transparency and granularity in Exchange rules.

Non-Displayed Limit Order. The Exchange proposes to offer the Non-

Displayed Limit Order for options trading on Pillar, which would be new for options trading and would provide OTP Holders and OTP Firms with a non-displayed order type in lieu of non-displayed PNP Blind Orders, which latter order type would not be available on Pillar.⁷³ The proposed order type would function similarly to the existing Non-Displayed Limit Order as described in Rule 7.31–E(d)(2). Proposed Rule 6.62P–O(d)(2) would define a Non-Displayed Limit Order as a Limit Order that is not displayed, does not route, and is ranked under the proposed category of “Priority 3—Non-Display Orders”; and that a Non-Displayed Limit Order may be designated Day or GTC and would not participate in any Auctions. This proposed rule text uses the same Pillar terminology as used in Rule 7.31–E(d)(2) with differences to reflect that the GTC Time-in-Force Modifier is available for options trading on Pillar.

- Proposed Rule 6.62P–O(d)(2)(A) would provide that the working price of a Non-Displayed Limit Order would be assigned on arrival and adjusted when resting on the Consolidated Book and that the working price of a Non-Displayed Limit Order to buy (sell) would be the lower (higher) of the limit price or the NBO (NBB). This proposed rule text is based on Rule 7.31–E(d)(2)(A) with non-substantive differences to reference the Consolidated Book instead of the NYSE Arca Book and to streamline the rule text without any substantive differences.

All-or-None (“AON”) Order. AON Orders are currently defined in Rule 6.62–O(d)(4). AON Orders are not available on the Exchange’s cash equity market, and for options trading on Pillar, would function similarly to how AON Orders currently function because such orders would only execute if they can be satisfied in their entirety. However, unlike the OX system, where AON Orders are not integrated in the Consolidated Book, on Pillar, the Exchange proposes that AON Orders would be ranked in the Consolidated Book and function as conditional orders that would trade only if their condition could be met, similar to how orders with a Minimum Trade Size (“MTS”) Modifier function on Pillar on the Exchange’s cash equity market. In addition, on Pillar, the Exchange would not support Market Orders designated as

AON, which would be a change from current functionality. The Exchange does not believe it needs to continue offering AON Market Orders because such functionality was not used often on the OX system, indicating a lack of market participant interest in this functionality. Because of the new functionality that would be available for AON Orders on Pillar, the Exchange proposes to use Pillar terminology to describe this order type.

Proposed Rule 6.62P–O(d)(3) would provide that an AON Order is a Limit Order that is to be traded in whole on the Exchange at the same time or not at all, which represents current functionality as described in the first sentence of Rule 6.62–O(d)(4). Proposed Rule 6.62P–O(d)(3) would further provide that an AON Order that does not trade on arrival would be ranked under the proposed category of “Priority 3—Non-Display Orders” and that an AON Order may be designated Day or GTC, does not route, and would not participate in any Auctions. This proposed rule text uses Pillar terminology to describe the proposed new functionality that such orders would be ranked on the Consolidated Book.

- Proposed Rule 6.62P–O(d)(3)(A) would provide that the working price of an AON Order would be assigned on arrival and adjusted when resting on the Consolidated Book and that the working price of an AON Order to buy (sell) would be the lower (higher) of the limit price or NBO (NBB). Because an AON Order is non-displayed, the Exchange proposes that its working price should be adjusted in the same manner as the proposed Non-Displayed Limit Order.

- Proposed Rule 6.62P–O(d)(3)(B) would provide that an Aggressing AON Order to buy (sell) would trade with sell (buy) orders and quotes that in the aggregate can satisfy the AON Order in its entirety. This proposed rule text is new and promotes clarity in Exchange rules that an Aggressing AON Order (whether on arrival or as a resting order that becomes an Aggressing Order) would be eligible to trade with more than one contra-side order or quote, provided that multiple orders and quotes in the aggregate would satisfy the AON Order in its entirety.

- Proposed Rule 6.62P–O(d)(3)(C) would provide that a resting AON Order to buy (sell) would trade with an Aggressing Order or Aggressing Quote to sell (buy) that individually can satisfy the whole AON Order. This is proposed new functionality, because currently, an AON Order can trade only against resting interest in the Consolidated Book. The Exchange believes this

⁷³ The Exchange notes that a Non-Displayed Limit Order would function similarly to a PNP Blind Order that locks or crosses the contra-side NBBO. In such case, a PNP Blind Order is not displayed, as described in Rule 6.62–O(u) (“if the PNP Blind Order would lock or cross the NBBO, the price and size of the order will not be disseminated”).

proposed change would provide an AON Order with additional execution opportunities.

- Proposed Rule 6.62P–O(d)(3)(C)(i) would provide that if an Aggressing Order or Aggressing Quote to sell (buy) does not satisfy the resting AON Order to buy (sell), that Aggressing Order or Aggressing Quote would not trade with and may trade through such AON Order. Proposed Rule 6.62P–O(d)(3)(C)(ii) would further provide that if a resting non-displayed order to sell (buy) does not satisfy the quantity of a same-priced resting AON Order to buy (sell), a subsequently arriving order or quote to sell (buy) that satisfies the AON Order would trade before such resting non-displayed order or quote to sell (buy) at that price. Both of these proposed rules are similar to current Rule 6.62–O(d)(4), which provides that a resting AON Order can be ignored if its condition is not met. Similar to current functionality, even though an AON would be ranked in the Consolidated Book, it is still a conditional order type and therefore, by its terms, can be skipped over for an execution. This proposed rule text is also based on how the MTS Modifier functions on the cash equity market, as described in Rule 7.31–E(i)(3)(E)(i) and (ii).

- Proposed Rule 6.62P–O(d)(3)(D) would provide that a resting AON Order to buy (sell) would not be eligible to trade against an Aggressing Order or Aggressing Quote to sell (buy): (i) At a price equal to or above (below) any orders or quotes to sell (buy) that are displayed at a price equal to or below (above) the working price of such AON Order; or (ii) at a price above (below) any orders or quotes to sell (buy) that are not displayed and that have a working price below (above) the working price of such AON Order. This proposed rule text is new functionality for AON Orders that is designed to protect the priority of resting orders and quotes and is based on how the MTS Modifier functions on the cash equity market, as described in Rule 7.31–E(i)(3)(C) and its subparagraphs (i) and (ii).

- Proposed Rule 6.62P–O(d)(3)(E) would provide that if a resting AON Order to buy (sell) becomes an Aggressing Order it would trade as provided in paragraph (d)(3)(B) of this Rule; however, other resting orders or quotes to buy (sell) ranked Priority 3—Non-Display Orders that become Aggressing Orders or Aggressing Quotes at the same time as the resting AON Order would be processed before the AON Order. This is proposed new functionality and is designed to promote

clarity in Exchange rules that if multiple orders ranked Priority 3—Non-Display Orders, including AON and non-AON Orders, become Aggressing Orders or Aggressing Quotes at the same time, the AON Order would not be eligible trade until the other orders ranked Priority 3—Non-Display Orders have been processed, even if they have later working times. The Exchange believes that it would be consistent with the conditional nature of AON Orders for other same-side non-displayed orders to have a trading opportunity before the AON Order.

Stop Order. Stop Orders are currently defined in Rule 6.62–O(d)(1). The Exchange proposes to use Pillar terminology with more granularity to describe Stop Orders in proposed Rule 6.62P–O(d)(4), with differences described below.

Proposed Rule 6.62P–O(d)(4) would provide that a Stop Order is an order to buy (sell) a particular option contract that becomes a Market Order (or is “elected”) when the Exchange BB (BO) or the most recent consolidated last sale price reported after the order was placed in the Consolidated Book (the “Consolidated Last Sale”) (either, the “trigger”) is equal to or higher (lower) than the specified “stop” price. The proposed functionality is similar to existing functionality and provides more granularity of the circumstances when a Stop Order would be elected.⁷⁴ Because a Stop Order becomes a Market Order when it is elected, the Exchange proposes that when it is elected, it would be cancelled if it does not meet the validations specified in proposed Rule 6.62P–O(a)(1)(A) and if not cancelled, it would be assigned a Trading Collar. This is similar to current functionality, which is not described in the current rule describing Stop Orders, that once converted to a Market Order, such order is subject to the checks applicable in the current rule for Market Orders, *i.e.*, cancelling such order if there is no NBBO. The proposed rule references the checks that would be applicable to a Market Order on Pillar and thus adds greater granularity and transparency to Exchange rules.

Proposed Rule 6.62P–O(d)(4)(A) would provide that a Stop Order would be assigned a working time when it is received but would not be ranked or displayed in the Consolidated Book until it is elected and that once converted to a Market Order, the order would be assigned a new working time

⁷⁴ The current rule states that a Stop Order to buy (sell) will be triggered (*i.e.*, elected) if “trades at a price equal to or greater (less) than the specified ‘stop’ price on the Exchange or another Market Center.” See Rule 6.62–O(d)(1).

and be ranked Priority 1—Market Orders. The original working time assigned to a Stop Order would be used to rank multiple Stop Orders elected at the same time. This is consistent with the current rule, which provides that a Stop Order is not displayed and has no standing in any Order Process in the Consolidated Book, unless or until it is triggered. The proposed rule is designed to provide greater granularity and clarity.

Proposed Rule 6.62P–O(d)(4)(B) would specify additional events that are designed to limit when a Stop Order may be elected so that a Market Order does not trade during a period of pricing uncertainty:

- Proposed Rule 6.62P–O(d)(4)(B)(i) would provide that if not elected on arrival, a Stop Order that is resting would not be eligible to be elected based on a Consolidated Last Sale unless the Consolidated Last Sale is equal to or in between the NBBO. This proposed rule text provides additional transparency of when a resting Stop Order would be eligible to be elected.

- Proposed Rule 6.62P–O(d)(4)(B)(ii) would provide that a Stop Order would not be elected if the NBBO is crossed.

- Proposed Rule 6.62P–O(d)(4)(B)(iii) would provide that after a Limit State or Straddle State is lifted, the trigger to elect a Stop Order would be either the Consolidated Last Sale received after such state was lifted or the Exchange BB (BO).⁷⁵

Stop Limit Order. Stop Limit Orders are currently defined in Rule 6.62–O(d)(2). The Exchange proposes to use Pillar terminology with more granularity to describe Stop Limit Orders in proposed Rule 6.62P–O(d)(5), with differences described below.

Proposed Rule 6.62P–O(d)(5) would provide that a Stop Limit Order is an order to buy (sell) a particular option contract that becomes a Limit Order (or is “elected”) when the Exchange BB (BO) or the Consolidated Last Sale (either, the “trigger”) is equal to or higher (lower) than the specified “stop” price.⁷⁶ The proposed functionality is similar to existing functionality and provides more granularity of when a Stop Limit Order would be elected than the current Rule 6.62–O(d)(2) definition of Stop Limit Order. As further

⁷⁵ Rule 6.65A–O(a)(2) currently provides that the Exchange will not elect Stop Orders when the underlying NMS stock is either in a Limit State or a Straddle State, which would continue to be applicable on Pillar. The Exchange proposes a non-substantive amendment to Rule 6.65A–O(a)(2) to add a cross-reference to proposed Rule 6.62P–O(d)(4).

⁷⁶ The term “Consolidated Last Sale” is defined in proposed Rule 6.62P–O(d)(4).

proposed, a Stop Limit Order to buy (sell) would be rejected if the stop price is higher (lower) than its limit price. Because a Stop Limit Order becomes a Limit Order when it is elected, the Exchange proposes that when it is elected, it would be cancelled if it fails Limit Order Price Protection or a Price Reasonability Check and if not cancelled, it would be assigned a Trading Collar.⁷⁷ This functionality is similar to current functionality, though it is not explicitly stated in the current rule describing Stop Limit Orders. Specifically, both in the current OX System and as proposed on Pillar, once converted to a Limit Order, such order is subject to the checks applicable in the current rule for Limit Orders, *i.e.*, Limit Order Filter on the OX System. The proposed rule references the checks that would be applicable to a Limit Order on Pillar and thus adds greater granularity and transparency to Exchange rules.

Proposed Rule 6.62P–O(d)(5)(A) would provide that a Stop Limit Order would be assigned a working time when it is received but would not be ranked or displayed in the Consolidated Book until it is elected and that once converted to a Limit Order, the order would be assigned a new working time and be ranked under the proposed category of “Priority 2—Display Orders.” This functionality is consistent with the current rule, which provides that a Stop Limit Order is not displayed and has no standing in any Order Process in the Consolidated Book, unless or until it is triggered. The proposed rule is designed to provide greater granularity and clarity.

Proposed Rule 6.62P–O(d)(5)(B) would specify additional events that are designed to limit when a Stop Limit Order may be elected so that a Limit Order would not have a possibility of trading or being added to the Consolidated Book during a period of pricing uncertainty.

- Proposed Rule 6.62P–O(d)(5)(B)(i) would provide that if not elected on arrival, a Stop Limit Order that is resting would not be eligible to be elected based on a Consolidated Last Sale unless the Consolidated Last Sale is equal to or in between the NBBO.

- Proposed Rule 6.62P–O(d)(5)(B)(ii) would provide that a Stop Limit Order would not be elected if the NBBO is crossed.

Orders with Instructions Not to Route. Currently, the Exchange defines non-routable orders in Rule 6.62–O as a PNP Order (which includes a Repricing PNP Order (“RPNP”)) (current Rule 6.62–

O(p)), a Liquidity Adding Order (“ALO”) (which includes a Repricing ALO (“RALO”)) (current Rule 6.62–O(t)); a PNP-Blind Order (current Rule 6.62–O(u)); and a PNP-Light Order (Rule 6.62–O(v)). The Exchange also defines Intermarket Sweep Orders (current Rule 6.62–O(aa)), which are also non-routable.

The Exchange separately defines non-routable quotes in Rule 6.37A–O as a Market Maker—Light Only Quotation (“MMLO”) (current Rule 6.37A–O(a)(3)(A)); a Market Maker—Add Liquidity Only Quotation (“MMALO”) (current Rule 6.37A–O(a)(3)(B)); and a Market Maker—Repricing Quotation (“MMRP”) (current Rule 6.37A–O(a)(3)(C)).

On Pillar, the Exchange proposes to streamline the non-routable order types and quotes that would be available for options trading, use terminology that is similar to how non-routable orders are described for cash equity trading as described in Rule 7.31–E(e), and describe the functionality that would be applicable to both orders and quotes in proposed Rule 6.62P–O(e). As described in greater detail below, proposed Rule 6.37A–O governing Market Maker Quotations would no longer define how quotations would function. Instead, that rule would specify that a Market Maker may designate either a Non-Routable Limit Order or ALO Order as a Market Maker quote. Because the way in which non-routable orders and quotes would function on Pillar would be virtually identical (with differences described below), and because Market Makers could enter a Non-Routable Limit Order or an ALO Order and then choose to designate it either as a quote or an order, the Exchange believes that it would promote transparency in Exchange rules to consolidate the description of the functionality in a single rule and eliminate duplication in Exchange rules. As described below, proposed Rule 6.37A–O would cross reference proposed Rule 6.62P–O(e).

On Pillar, the Exchange would no longer offer functionality based on the PNP-Blind Order, PNP-Light Order, or MMLO because it believes that the proposed orders/quotes with instructions not to route on Pillar would provide OTP Firms and OTP Holders with the core functionality associated with these existing order types, including that the proposed rules would provide for non-routable functionality and the ability to either reprice or cancel such orders/quotes. In addition, as discussed above, the Exchange believes that the proposed Non-Displayed Limit Order would provide functionality similar to what is

currently available with the PNP-Blind Order.

Non-Routable Limit Order. Proposed Rule 6.62P–O(e)(1) would define the Non-Routable Limit Order. As explained further below, this proposed order type incorporates functionality currently available in both the existing PNP and RPNP order types, as defined in Rule 6.62–O, and the existing MMRP quotation type, as defined in Rule 6.37A–O(a)(3)(C),⁷⁸ and uses Pillar terminology. As described below, a Market Maker can designate a Non-Routable Limit Order as either a quote or an order. Accordingly, references to the capitalized term “Non-Routable Limit Order” describes functionality for either a quote or an order, unless otherwise specified.

Proposed Rule 6.62P–O(e)(1) would provide that a Non-Routable Limit Order is a Limit Order or quote that does not route and may be designated Day or GTC and would further provide that a Non-Routable Limit Order with a working price different from the display price would be ranked under the proposed category of “Priority 3—Non-Display Orders” and a Non-Routable Limit Order with a working price equal to the display price would be ranked under the proposed category of “Priority 2—Display Orders.” This proposed rule uses Pillar terminology and describes functionality similar to the way in which a Non-Routable Limit Order is described for the Exchange’s cash equity market in Rules 7.31–E(e)(1) and 7.31–E(e)(1)(B), including references to the Pillar concepts of “working” and “display” price as well to Priority rankings as proposed in Rule 6.76P–O(e)(2), (3). This proposed rule describes functionality similar to that described in the first clause of current Rule 6.62–O(p) relating to a PNP Order, which states that the portion of such order not executed on arrival is ranked in the Consolidated Book without routing any portion of the order to another Market Center.

Proposed Rule 6.62P–O(e)(1)(A) would provide that a Non-Routable Limit Order would not be displayed at a price that would lock or cross an Away Market NBBO and that a Non-Routable Limit Order to buy (sell) would trade with orders or quotes to sell (buy) in the Consolidated Book priced at or below (above) the Away Market NBO (NBB). This proposed text is designed to provide granularity that a Non-Routable

⁷⁸ Both RPNPs and MMRPs function similarly. Compare current Rule 6.37A–O(a)(4)(B) and subparagraphs (i) and (ii) with current Rule 6.62–O(p)(1)(A) and subparagraphs (i) and (ii). They are defined in separate rules only because the former is for quotes and the latter for orders.

⁷⁷ See discussion *infra*, regarding proposed Rule 6.41P–O and Price Reasonability Checks.

Limit Order would never be displayed at a price that would lock or cross an Away Market NBBO, which is consistent with current PNP and RPNP functionality described in Rules 6.62–O(p) and (p)(1). The Exchange proposes to use the term “Away Market NBBO” to provide more granularity in Exchange rules.

Proposed Rule 6.62P–O(e)(1)(A)(i) would provide that a Non-Routable Limit Order can be designated to be cancelled if it would be displayed at a price other than its limit price. This would be an optional designation and would provide OTP Holders and OTP Firms with functionality similar to how a PNP Order currently functions, which cancels if it locks or crosses the NBBO.⁷⁹ The Exchange proposes a substantive difference from the current PNP Order functionality such that if an OTP Holder or OTP Firm opts to cancel instead of reprice a Non-Routable Limit Order, such order would be cancelled only if it could not be displayed at its limit price—which could be because the order would be repriced to display at a price that would not lock or cross an Away Market NBBO or because it would be repriced due to Trading Collars.⁸⁰ Stated otherwise, if a Non-Routable Limit Order with a designation to cancel could be displayed at its original limit price and not lock or cross an Away Market NBBO, such order would not be cancelled. The Exchange believes that the proposed rule provides more granularity of the circumstances when a Non-Routable Limit Order could be cancelled, if so designated. This proposed functionality would be new on Pillar and is not currently available for cash equity trading.

Proposed Rule 6.62P–O(e)(1)(A)(ii) would provide that if not designated to cancel, if the limit price of a Non-Routable Limit Order to buy (sell) would lock or cross an Away Market NBO (NBB), it would be repriced to have a working price equal to the Away Market NBO (NBB) and a display price

one MPV below (above) that NBO (NBB). Accordingly, the proposed Non-Routable Limit Order, if not designated to cancel, would reprice in the same manner as an RPNP order or MMRP quotation reprices on arrival per Rules 6.62–O(p)(1)(A) and 6.37A–O(a)(4)(A), which both offer similar functionality.

The Exchange proposes new functionality on Pillar for the Non-Routable Limit Order as compared to either the RPNP Order on OX or the Non-Routable Limit Order on the Exchange’s cash equity market. Specifically, proposed Rule 6.62P–O(e)(1)(B) would provide that the display price of a resting Non-Routable Limit Order to buy (sell) that has been repriced would be repriced higher (lower) only one additional time.⁸¹ If after that repricing, the display price could be repriced higher (lower) again, the order can be designated to either remain at its last working price and display price or be cancelled, provided that a resting Non-Routable Limit Order that is designated as a quote cannot be designated to be cancelled.⁸²

The Exchange notes that this designation to cancel is separate from the designation to cancel if it cannot be displayed at its limit price. If a Non-Routable Limit Order is designated to cancel if it cannot be displayed at its limit price, this second cancellation designation would not be needed as the order would have already been cancelled. Rather, this second cancellation designation is applicable only to a resting Non-Routable Limit Order that has been designated to reprice on arrival and was repriced before it was displayed on the Consolidated Book, and provides OTP Holders and OTP Firms with an option to cancel a resting order if market conditions were such that a resting order could have been repriced again, e.g., the contra-side Away Market NBBO changes. To assist Market Makers in maintaining quotes in their assigned

series, the Exchange proposes that this second cancellation designation would not be available to Market Makers for Non-Routable Orders designated as a Market Maker quote.⁸³

Proposed Rule 6.62P–O(e)(1)(B)(i) would provide that if the limit price of the resting Non-Routable Limit Order to buy (sell) that has been repriced no longer locks or crosses the Away Market NBO (NBB), it would be assigned a working price and display price equal to its limit price. This proposed rule text is based on the way in which Non-Routable Limit Orders function on the Exchange’s cash equity market, as described in Rule 7.31–E(e)(1)(A)(iv), with a difference that the proposed rule does not include text describing that, in such circumstances, the order “will not be assigned a new working price or display price based on changes to the PBO (PBB).” The Exchange does not propose to include this text because it is redundant of proposed Rule 6.76P–O(b)(3), which describes that once an order is displayed, it can stand its ground if it is locked or crossed by the Away Market PBBO.⁸⁴

Proposed Rule 6.62P–O(e)(1)(B)(ii) would provide that the working price of a resting Non-Routable Limit Order to buy (sell) that has been repriced would be adjusted to be equal to its display price if the Away Market NBO (NBB) is equal to or lower (higher) than its display price. This proposed rule is based in part on how an RPNP reprices when the NBO (NBB) updates to lock or cross its display price (as described in Rule 6.62–O(p)(1)(A)(i)) and uses Pillar terminology (*i.e.*, Away Market NBBO and concepts of working price and display price).⁸⁵ The proposed rule would further provide that once the working price and display price of a Non-Routable Limit Order to buy (sell) are the same, the working price would be adjusted higher (lower) only if the display price of the order is adjusted.⁸⁶

⁷⁹ Proposed Rules 6.37AP–O(b) and (c) set forth the continuous quoting obligations of Lead Market Makers and Market Makers, respectively.

⁸⁰ See discussion *supra* regarding proposed Rule 6.76P–O(b)(3), which describes how the Exchange would not change the display price of any Limit Orders or quotes ranked under the proposed category of “Priority 2—Display Orders.”

⁸¹ Rule 6.62–O(p)(1)(A)(i) provides that “if the NBO (NBB) updates to lock or cross the RPNP’s display price, such RPNP will trade at its display price in time priority behind other eligible interest already displayed at that price.” On Pillar, if the NBO (NBB) updates to lock or cross the display price of a Non-Routable Order, and the working price is adjusted to be equal to the display price, the order will not receive a new working time. See discussion *supra* regarding proposed Rule 6.76P–O(f)(2)(B).

⁸² For example, if the Away Market NBO is 1.05 and the Exchange receives a Non-Routable Limit

⁷⁹ A PNP Order cannot route and any unexecuted portion is ranked in the Consolidated Book except that such order is canceled if it would lock or cross the NBBO. See Rule 6.62–O(p).

⁸⁰ Current Rule 6.62–O(p)(1)(B) provides that an incoming RPNP order would cancel if its limit price is more than a configurable number of MPVs outside its initial display price (on arrival). Under Pillar, because Trading Collars would be applicable to Non-Routable Limit Orders (and such orders may be repriced or “collared” on arrival), the Exchange does not propose to cancel an incoming Non-Routable Limit Order if its limit price is more than a configurable number of MPVs outside its initial display price. As such, this aspect of RPNP functionality is not incorporated in the proposed Pillar rules and the Exchange instead proposes to incorporate Trading Collar functionality into the Non-Routable Limit Order.

⁸¹ For example, on arrival, a Non-Routable Limit Order to buy (sell) with a limit price higher (lower) than the NBO (NBB), would have a display price one MPV below (above) the NBO (NBB) and a working price equal to the NBO (NBB). If the Away Market NBO (NBB) reprices higher (lower), the resting Non-Routable Limit Order to buy (sell) would similarly be repriced higher (lower). If the NBO (NBB) adjusts higher (lower) again, the resting Non-Routable Limit Order would not be adjusted again.

⁸² The working time of a Non-Routable Limit Order would be adjusted as described in proposed Rule 6.76P–O(f)(2), which would be applicable to any scenario when the working time of an order may change, including a Non-Routable Limit Order. Similar to how the Pillar rules function on the Exchange’s cash equity market, the Exchange does not propose to separately describe how the working time of an order changes in proposed Rule 6.62P–O.

Finally, proposed Rule 6.62P–O(e)(1)(C) would provide that the designation to cancel a Non-Routable Limit Order would not be applicable in an Auction and such order would participate in an Auction at its limit price. This proposed rule text promotes clarity and transparency that a Non-Routable Limit Order would be eligible to participate in an Auction, but that it would be repriced to its limit price for participation in such Auction, which is consistent with current RPNP functionality, as described in the last sentence of Rule 6.62–O(p) and providing that an RPNP would be processed as a Limit Order and would not be repriced for purposes of participating in an opening or reopening auction.

ALO Order. Proposed Rule 6.62P–O(e)(2) would define an ALO Order as a Limit Order or quote that is a Non-Routable Limit Order that would not remove liquidity from the Consolidated Book. This proposed order type incorporates functionality currently available in the existing ALO and RALO order types, as defined in Rule 6.62–O(t), and the existing MMALO quotation type, as defined in Rule 6.37A–O(a)(3)(B), with differences described below, including an option to cancel or reprice an ALO Order if such non-routable interest would trade as a liquidity taker. Unless otherwise specified in proposed Rule 6.62P–O(e)(2), an ALO Order would function the same as a Non-Routable Limit Order, including that it would participate in an Auction at its limit price. As described below, per proposed Rule 6.37AP–O, a Market Maker can designate an ALO Order as either a quote or an order. Accordingly, references to the capitalized term “ALO Order” describe functionality for both quotes and orders.

Proposed Rule 6.62P–O(e)(2)(A) would provide that an ALO Order would not be displayed at a price that would lock or cross an Away Market NBBO, would lock or cross displayed interest in the Consolidated Book, or would cross non-displayed interest in the Consolidated Book. Because an ALO Order would never remove liquidity, this proposed rule text ensures that such order would not be displayed at a price that would lock or cross displayed interest either on the Exchange or an

Order to buy priced at 1.10, it would be assigned a display price of 1.00 and a working price of 1.05. If the Away Market NBO adjusts to 1.00, the working price of the Non-Routable Limit Order to buy would be adjusted to 1.00 to be equal to its display price. However, if the Away Market NBO moves back to 1.05, the Non-Routable Limit Order's working price would not adjust again to 1.05 and would stay at 1.00.

Away Market, and would not be displayed at a price that crosses non-displayed interest in the Consolidated Book. This proposed rule text is consistent with current functionality, as described for MMALO in Rule 6.37–O(a)(3)(B) and for ALO in Rule 6.62–O(t), that such quotes or orders would not trade as takers.

Proposed Rule 6.62P–O(e)(2)(A)(i) would provide that an ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price. This proposed designation to cancel would be optional and an ALO Order so designated would function similarly to a Liquidity Adding Order, as defined in Rule 6.62–O(t), which is rejected if it would be marketable against the NBBO.

Proposed Rule 6.62P–O(e)(2)(A)(ii) would provide that an ALO Order to buy (sell) would be displayed at its limit price if it locks non-displayed orders or quotes to sell (buy) on the Consolidated Book. This proposed functionality would be new for options trading on Pillar.⁸⁷ Allowing a conditional order to lock interest in the Consolidated Book is consistent with current functionality for other non-displayed orders. For example, an AON is a non-displayed conditional order type that could be priced to trade at a price that locks contra-side interest, but the interest would not interact if the AON condition could not be satisfied, in which case, two orders with locking prices, one that is non-displayed, would both be accepted by the Exchange. The proposed ALO Order is also a conditional order type because it can never be a liquidity taker. The Exchange believes that allowing an ALO Order to lock non-displayed interest would reduce potential repricing or cancellation events for an incoming ALO Order and would likewise reduce potential information leakage about non-displayed interest in the Consolidated Book. This behavior is also consistent with how ALO Orders function on the Exchange's cash equity platform.⁸⁸ Because an ALO Order would not be repriced in this scenario, this functionality would be the same regardless of whether the ALO Order includes the optional designation to cancel.

Proposed Rule 6.62P–O(e)(2)(A)(iii) would provide that an ALO Order to

⁸⁷ Currently, an order designated as a RALO to buy (sell) that would trade with any undisplayed sell (buy) interest will be displayed at a price one MPV below (above) that undisplayed sell interest. See Rule 6.62–O(t)(1)(A). See also Rule 6.37A–O(a)(4)(A)(i) (describing similar functionality for a quote designated as a MMALO).

⁸⁸ See, e.g., Rule 7.31–E(e)(2)(B)(iv).

buy (sell) would not consider an AON Order or an order with an MTS Modifier to sell (buy) for purposes of determining whether it needs to be repriced or cancelled. This proposed rule would be new functionality and is designed to promote transparency that a resting contra-side order with conditional instructions, *i.e.*, an AON Order or an order with an MTS Modifier, would not have any bearing on whether an Aggressing ALO Order would need to be repriced. Accordingly, an ALO Order would not trade as the liquidity taker with such orders (even if it could satisfy their size condition) and could be displayed at a price that would lock or cross the price of such orders. Once the ALO Order is resting on the Consolidated Book, the Exchange would reevaluate the orders on the Consolidated Book. For example, if the ALO Order could satisfy the size condition of the resting AON Order, the resting AON Order would become the Aggressing Order and would trade as the liquidity taker with such resting ALO Order.

Proposed Rule 6.62P–O(e)(2)(B) would describe how an ALO Order would be processed if it is not designated to cancel, as follows:

- If the limit price of an ALO Order to buy (sell) would lock or cross displayed orders or quotes to sell (buy) on the Consolidated Book, it would be repriced to have a working price and display price one MPV below (above) the lowest (highest) priced displayed order or quote to sell (buy) on the Consolidated Book (proposed Rule 6.62P–O(e)(2)(B)(i)). This proposed rule is consistent with how both RALO and MMALO reprice under current rules.⁸⁹
- If the limit price of an ALO Order to buy (sell) would lock or cross an Away Market NBO (NBB), it would be repriced to have a working price equal to the Away Market NBO (NBB) and a display price one MPV below (above) the NBO (NBB) (proposed Rule 6.62P–O(e)(2)(B)(ii)). This proposed functionality is consistent with how both RALO and MMALO reprice under current rules.⁹⁰
- If the limit price of an ALO Order to buy (sell) would cross non-displayed

⁸⁹ Current Rule 6.62–O(t)(1) provides that a RALO will be repriced instead of rejected if it would trade as a liquidity taker or display at a price that locks or crosses any interest on the Exchange or the NBBO. Current Rule 6.62–O(t)(1)(A) further provides that if an RALO would trade with any displayed or undisplayed contra-side interest on the Consolidated Book, it would be displayed at a price one MPV inside such interest. See also Rule 6.37–O(a)(4)(A)(i).

⁹⁰ See Rules 6.62–O(t)(1)(A) and 6.37A–O(a)(4)(A)(i).

orders or quotes⁹¹ on the Consolidated Book, it would be repriced to have a working price and display price equal to the lowest (highest) priced non-displayed order or quote to sell (buy) on the Consolidated Book (proposed Rule 6.62P–O(e)(2)(B)(iii)). This functionality would be new on Pillar for options trading and would provide that an ALO Order would never take liquidity thereby eliminating the potential for an ALO to cross non-displayed interest in the Consolidated Book. This proposed functionality is therefore different not only from how RALOs and MMALOs currently function, but is also different from how ALO Orders currently function on the Exchange's cash equity market.⁹² For the reasons discussed above, the Exchange believes that displaying ALO Orders at a price that locks the best-priced non-displayed interest would reduce potential information leakage about the non-displayed orders on the Consolidated Book.

Because an ALO would never be a liquidity-taking order, the above-described repricing scenarios provide clarity and transparency regarding how an ALO Order would be repriced (or cancelled, if this optional designation is selected) to prevent either trading with interest on the Consolidated Book or routing to an Away Market. Accordingly, with the exception of how an ALO Order that locks or crosses non-displayed interest would be processed, the proposed ALO Order would be consistent with the current functionality available for RALO, as described in Rule 6.62–O(t)(1)(A) and for MMALO, as described in Rule 6.37–O(a)(4)(A).

Proposed Rule 6.62P–O(e)(2)(C) would provide that the display price of a resting ALO Order to buy (sell) that has been repriced would be repriced higher (lower) only one additional time and that if, after that repricing, the display price could be repriced higher (lower) again, the order can be designated to either remain at its last working price and display price or be cancelled, provided that a resting ALO Order that is a quote cannot be designated to be cancelled. This proposed functionality would be new to Pillar and is based on how the proposed Non-Routable Limit Order would function, as described above.⁹³

Proposed Rule 6.62P–O(e)(2)(C)(i) would provide that if the limit price of an ALO Order to buy (sell) that has been repriced no longer locks or crosses displayed orders or quotes in the Consolidated Book, locks or crosses the Away Market NBBO, or crosses non-displayed orders or quotes in the Consolidated Book, it would be assigned a working price and display price equal to its limit price. This proposed rule text is similar to proposed Rule 6.62P–O(e)(1)(B)(i) for Non-Routable Limit Orders, with differences to reflect the additional circumstances when an ALO Order would be repriced based off of contra-side displayed or non-displayed interest in the Consolidated Book because, unlike a Non-Routable Limit Order, an ALO Order would not trade as a liquidity taker. The proposed rule is designed to provide granularity and clarity regarding when a resting ALO Order would be assigned a working price and display price equal to its limit price.⁹⁴

Proposed Rule 6.62P–O(e)(2)(D) would provide that the working price of a resting ALO Order to buy (sell) that has been repriced would be adjusted to be equal to its display price (and would not be adjusted again unless the display price of the order is adjusted) if:

- The Away Market NBO (NBB) re-prices to be equal to or lower (higher) than the display price of the resting ALO Order to buy (sell) (proposed Rule 6.62P–O(e)(2)(D)(i)); or
- an ALO Order or Day ISO ALO to sell (buy) is displayed on the Consolidated Book at a price equal to the working price of the resting ALO Order to buy (sell) (proposed Rule 6.62P–O(e)(2)(D)(ii)).

This proposed rule text is similar to proposed Rule 6.62P–O(e)(1)(C) for Non-Routable Limit Orders, with differences to reflect the additional circumstances when an ALO Order would be repriced as a result of contra-side interest on the Consolidated Book so that the ALO Order would not be a liquidity taker. Specifically, the Exchange proposes that for an ALO Order that has been repriced and has a non-displayed working price, if the Exchange receives a contra-side ALO Order (or Day ISO ALO) with a limit price that is equal to or crosses the working price of the resting ALO Order, the working price of the resting ALO

Order would be adjusted to be equal to its display price. This proposed functionality would reduce the potential for two contra-side ALO Orders to have working prices that are locked on the Consolidated Book. The proposed rule text is designed to provide more granularity than the current Rule regarding circumstances when an ALO Order would be repriced.

Proposed Rule 6.62P–O(e)(2)(E) would provide that when the working price and display price of an ALO Order to buy (sell) are the same, the working price would be adjusted higher (lower) only if the display price of the order is adjusted. This proposed functionality would be new for Pillar and is not currently available on the Exchange's cash equity platform.

Proposed Rule 6.62P–O(e)(2)(F) would provide that the ALO designation would be ignored for ALO Orders that participate in an Auction. This proposed rule is based on Rule 7.31–E(e)(2)(A), which similarly provides that an ALO Order can participate in an auction and that its ALO designation would be ignored. This is also new functionality for options because currently, the Exchange rejects ALOs if entered outside of Core Trading Hours or during a trading halt and if resting, are cancelled during a trading halt. The Exchange proposes this new functionality to provide such ALO Orders with an execution opportunity in an Auction.

Intermarket Sweep Order (“ISO”). ISOs are currently defined in Rule 6.62–O as a Limit Order for an options series that instructs the Exchange to execute the order up to the price of its limit, regardless of the Away Market Protected Quotations⁹⁵ and that ISOs may only be entered with a time-in-force of IOC, and the entering OTP Holder must comply with the provisions of Rule 6.92–O(a)(8). The Exchange proposes to offer identical functionality on Pillar and to describe such functionality in proposed Rule 6.62P–O(e)(3) using Pillar terminology, including that an ISO is a Limit Order that does not route and meets the requirements of Rule 6.92–O(a)(8).

Currently, an ISO must be entered with a time-in-force of IOC. On Pillar, the Exchange proposes to add the ability for an OTP Holder or OTP Firm to

⁹¹ For example, a contra-side Market Maker quote designated as a Non-Routable Limit Order could have a non-displayed working price.

⁹² See Rule 7.31–E(e)(2)(B)(ii).

⁹³ This proposed feature to limit the number of times an ALO may be repriced differs from the treatment of RALOs, which may be continuously repriced (both the displayed and undisplayed price)

as interest in the Consolidated Book or NBBO moves. See Rule 6.62–O(t)(1)(A).

⁹⁴ The proposed rule is similar to RALO functionality currently described in Rule 6.62–O(t)(1)(A)(ii) (if the NBO (NBB) updates to lock or cross the RALO's display price, such RALO will trade at its display price”). See also Rule 6.37A–O(a)(4)(A)(i)(b) (describing similar functionality for MMALO).

⁹⁵ The terms “Protected Bid,” “Protected Offer,” and “Quotation” are defined in Rule 6.92–O(a)(15) and (16) and the term “Away Market” is defined in Rule 1.1. Accordingly, Away Market Protected Quotations refer to Protected Bids and Protected Offers that are disseminated pursuant to the OPRA Plan and are the Best Bid and Best Offer displayed by an Eligible Exchange, as those terms are defined in Rule 6.92–O.

designate an ISO either as IOC, which is current functionality, or with a Day time-in-force designation, which would be new for options trading. The Exchange also proposes to offer new functionality for options trading to designate a Day ISO as ALO. Both the proposed Day ISO and Day ISO ALO functionality are available on the Exchange's cash equity market as described in Rule 7.31–E(e)(3). The Exchange proposes to describe the functionality for each type of ISO separately, as follows:

- *IOC ISO.* Proposed Rule 6.62P–O(e)(3)(A) would define an IOC ISO as an ISO designated IOC to buy (sell) that would be immediately traded with orders and quotes to sell (buy) in the Consolidated Book up to its full size and limit price and may trade through Away Market Protected Quotations and any untraded quantity of an IOC ISO would be immediately and automatically cancelled. This proposed rule uses the same Pillar terminology as used in Rule 7.31–E(e)(3)(B) to describe functionality that would be offered on Pillar without any differences from how ISOs currently function. The Exchange proposes a non-substantive difference in the proposed Pillar options rule to reference that an IOC ISO may trade through Away Market Protected Quotations, which is consistent with both current options and cash equity platform functionality.

- *Day ISO.* Proposed Rule 6.62–O(e)(3)(B) would define a Day ISO as an ISO designated Day to buy (sell) that, if marketable on arrival, would be immediately traded with orders and quotes to sell (buy) in the Consolidated Book up to its full size and limit price and may trade through Away Market Protected Quotations and that any untraded quantity of a Day ISO would be displayed at its limit price and may lock or cross Away Market Protected Quotations at the time the Day ISO is received by the Exchange. As noted above, this proposed functionality (allowing Day designation for ISOs) would be new on the Exchange for options trading and would offer market participants additional control over their trading interest. The proposed rule is substantively identical to the Day ISO functionality available on the Exchange's cash equity market, as described in Rule 7.31–E(e)(3)(C), with a non-substantive difference to use the phrase “may lock or cross Away Market Protected Quotations at the time the Day ISO is received by the Exchange” instead of “may lock or cross a protected quotation that was displayed at the time of arrival of the Day ISO.” These proposed textual differences are designed to promote clarity and

transparency without any substantive differences. The availability of the Day time-in-force designation for ISOs would not be new for options trading, however, as such orders are currently available on other options exchanges.⁹⁶ The proposed Day ISO is also consistent with current Rule 6.95–O(b)(3), which describes an exception to the prohibition on locking or crossing a Protected Quotation if the Member simultaneously routed an ISO to execute against the full displayed size of any locked or crossed Protected Bid or Protected Offer.⁹⁷ Although the Exchange has not previously availed itself of this exception, this exception to locking and crossing Protected Bids and Protected Offers would only be needed if an ISO is designated as Day and therefore would be displayed at a price that would lock or cross a Protected Quotation; an IOC ISO would never be displayed and therefore this existing exception would not be applicable to such orders.

- *Day ISO ALO.* Proposed Rule 6.62P–O(e)(3)(C) would define a Day ISO ALO as a Day ISO with an ALO modifier. This proposed order type would be new for options trading and is based on the Day ISO ALO currently available on the Exchange's cash equity market, as described in Rule 7.31–E(e)(3)(D), with differences to reflect how the order type would function on the Exchange's options market. Specifically, similar to the differences between the proposed ALO Order for options trading on Pillar, as compared

⁹⁶ See Nasdaq Options 3, Section 7(a)(7) (“ISOs may have any time-in-force designation . . .”) and Cboe Rules 5.30(a)(2) and (3). See also Cboe US Options Fix Specifications, dated June 15, 2021, Section 4.4.7, available here: http://cdn.cboe.com/resources/membership/US_Options_FIX_Specification.pdf, which references how a Day ISO would be processed under specified circumstances.

⁹⁷ The Commission has previously stated that the requirements in the Options Linkage Plan relating to Locked and Crossed Markets are “virtually identical to those applicable to market centers for NMS stock under Regulation NMS.” See also Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362, 39368 (August 6, 2009) (Order approving Options Linkage Plan). Accordingly, guidance relating to the ISO exception for locked and crossed markets for NMS stocks that specifically contemplate use of Day ISOs is also applicable to options trading. See Responses to Frequently Asked Questions Concerning Rule 611 and Rule 610 of Regulation NMS, FAQ 5.02 (“The ISO exception to the SRO lock/cross rules, in contrast, requires that ISOs be routed to execute against all protected quotations with a price that is equal to the display price (i.e., those protected quotations that would be locked by the displayed quotation), as well as all protected quotations with prices that are better than the display price (i.e., those protected quotations that would be crossed by the displayed quotation).” Consistent with this guidance, the Exchange implemented Rule 6.95–O(b)(3). See also Cboe Rule 5.67(b)(3), and Nasdaq Options 5, Section 3(b)(3).

to the cash equity version of the ALO Order, for options trading, a Day ISO with an ALO designation would not trade as liquidity taker.

As proposed, on arrival, a Day ISO ALO to buy (sell) may lock or cross Away Market Protected Quotations, but would not remove liquidity from the Consolidated Book, which is how the Exchange proposes that ALO Orders would function on Pillar and consistent with current options functionality for RALO as described herein.⁹⁸ A Day ISO ALO to buy (sell) can be designated to be cancelled if it would be displayed at a price other than its limit price, which is similar to the proposed cancellation instruction for ALO Orders for options trading on Pillar, described above. Proposed Rule 6.62P–O(e)(3)(C)(i) would provide that if not designated to cancel, a Day ISO ALO that would lock or cross orders and quotes on the Consolidated Book would be repriced as specified in proposed Rule 6.62P–O(e)(2)(B). This proposed rule therefore incorporates the proposed repricing functionality for ALO Orders for options trading on Pillar with the proposed Day ISO ALO. Proposed Rule 6.62P–O(e)(3)(C)(ii) would provide that, once resting, a DAY ISO ALO would be processed as an ALO Order as specified in proposed Rule 6.62P–O(e)(2)(C)–(G).

Complex Orders. Complex Orders are defined in Rule 6.62–O(e). The Exchange proposes to define Complex Orders for Pillar in proposed Rule 6.62P–O(f) based on Rule 6.62–O(e) and its sub-paragraphs (1) and (2) without any substantive differences. The Exchange proposes to add clarifying text that the different options series in a Complex Order are also referred to as the “legs” or “components” of the Complex Order. The Exchange also proposes that proposed Rule 6.62P–O(f) would provide that a Complex Order would be any order involving the simultaneous purchase and/or sale of “two or more options series in the same underlying security,” and not use the modifier “different” before the phrase “more option series.” The Exchange believes that the word “different” is redundant and unnecessary in this context. In addition, proposed Rule 6.62P–O(f)(1) and (2) would not reference mini-options contracts, which no longer trade on the Exchange.

Cross Orders. Currently, the only electronically-entered cross orders available on the Exchange are Qualified Contingent Cross Orders, which are

⁹⁸ By contrast, the Rule 7.31–E(e)(3)(D) description of Day ISO ALO for cash equity trading incorporates cash equity functionality that an order with an ALO would trade if it crosses the working price of any displayed or non-displayed orders.

defined in Rule 6.62–O(bb) and Commentary .02 to Rule 6.62–O. In addition, Rule 6.90–O describes how Qualified Contingent Cross Orders are processed. The Exchange proposes to define the term “Cross Orders” on Pillar in proposed Rule 6.62P–O(g). At this time, the only Cross Orders that would be available on Pillar for electronic entry would be Qualified Contingent Cross (“QCC”) Orders. As proposed, QCC Orders on Pillar would function identically to how Qualified Contingent Cross Orders function on the OX system, and for purposes of the rules governing trading on Pillar, the Exchange proposes to merge language from two rules relating to QCC Orders into a single rule, proposed Rule 6.62P–O(g), using Pillar terminology and functionality as described below. Proposed Rule 6.62P–O(g), (g)(1), and (g)(2) would describe rules generally applicable to electronically-entered Cross Orders and Complex Cross Orders and followed by more specific rules applicable to QCC, and Complex QCC, Orders in proposed Rule 6.62P–O(g)(3).

Proposed Rule 6.62P–O(g) would provide that “Cross Orders” would be two-sided order messages with instructions to match the identified buy-side with the identified sell-side at a specified price, which could either be designated as a limit price or at the market (“cross price”).⁹⁹ The proposed rule would further provide that a Cross Order that is not rejected per proposed Rule 6.62P–O(g)(1) or (2) would immediately trade in full at its cross price, would not route, and may be entered with an MPV of \$0.01 regardless of the MPV of the options series and that Cross Orders may be entered by Floor Brokers from the Trading Floor or routed to the Exchange from off-Floor. This proposed rule is consistent with current Rule 6.90–O, which provides that Qualified Contingent Cross Orders are automatically executed upon entry provided that they meet specified criteria. On Pillar, the Exchange proposes to specify those criteria in proposed Rule 6.62P–O(g)(1), described below. Finally, the proposed Rule would provide that Rule 6.47A–O (related to exposure of orders on the Exchange) does not apply to Cross Orders, which text is substantively

⁹⁹The Exchange does not currently offer Cross Orders on its cash equity market. This proposed rule text uses Pillar terminology that is based in part on NYSE Chicago Rule 7.31(g), which likewise describes “cross orders” as “[t]wo-sided orders with instructions to match the identified buy-side with the identified sell-side at a specified price (the ‘cross price’),” and goes on to describe functionality applicable to Cross Orders generally and then specify specific types of Cross Orders available on that exchange.

identical to Commentary .03 to current Rule 6.90–O.¹⁰⁰

Proposed Rule 6.62P–O(g)(1) would describe general rules relating to execution of Single-Leg Cross Orders (which would all be QCC Orders, described below) and would provide that a Cross Order with one option leg would be rejected if received when the NBBO is crossed or if it would be traded at a cross price that (i) is at the same price as a displayed Customer order on the Consolidated Book and (ii) is not at or between the NBBO. This proposed rule is based on Rule 6.90–O without any substantive differences. The Exchange believes that specifying that a Cross Order would be rejected when the NBBO is crossed, which is new text, provides greater granularity than current Rule 6.90–O(1), which provides that “Qualified Contingent Cross Orders will be automatically cancelled if they cannot be executed.” The other two proposed conditions are identical to the current functionality, as specified in Rule 6.90–O: That Qualified Contingent Cross Orders are automatically executed “provided that the execution (i) is not at the same price as a Customer Order in the Consolidated Book and (ii) is at or between the NBBO.”

Proposed Rule 6.62P–O(g)(1) would further set forth how a Cross Order designated to trade at the market would be priced. As proposed, a Cross Order with a cross price at the market would execute at the midpoint of the NBBO; provided that:

- If there is no NBB, a \$0.01 bid would be used (proposed Rule 6.62P–O(g)(1)(A));
- if there is displayed Customer interest priced equal to the NBB, NBO or both, the midpoint would be based on the BBO improved by \$0.01 for the side(s) containing displayed Customer interest (proposed Rule 6.62P–O(g)(1)(B));
- if there is no NBO, such order would be rejected (proposed Rule 6.62P–O(g)(1)(C)); or
- if the midpoint of the NBBO is in sub-pennies, the order would trade at the midpoint of the NBBO rounded to the nearest MPV for the series (proposed Rule 6.62P–O(g)(1)(D)).

This proposed rule text is designed to promote clarity and transparency in Exchange rules regarding how a Cross Order “at the market” would be processed, including in circumstances

¹⁰⁰Commentary .03 to Rule 6.90–O provides that “NYSE Arca Rule 6.47A–O does not apply to Qualified Contingent Cross Orders.” As noted above, at this time, the Exchange would only be offering QCC Cross Orders and therefore the proposed rule is substantively the same as this current Commentary.

when there is no NBB or NBO or there is displayed Customer interest equal to the NBBO.

Proposed Rule 6.62P–O(g)(2) would describe how Complex Cross Orders would be executed on the Exchange. At this time, the only Complex Cross Orders available for options trading on Pillar would be QCC. Accordingly, this proposed rule would describe how a Complex Cross Order that is QCC would trade. As proposed, a Complex Cross Order must include a limit price and would be rejected if:

- It is not priced within the Complex NBBO for the complex strategy.¹⁰¹ If there is displayed Customer interest on a given leg, the Complex NBB (NBO) for that leg would be calculated by increasing (decreasing) the NBB (NBO) by one penny (\$0.01) and then multiplying by the leg ratio. If there is no NBB for a given leg, a \$0.01 bid will be used to calculate the Complex NBB for that leg (proposed Rule 6.62P–O(g)(2)(A)). These proposed additional calculations for a Complex NBBO would be applicable only when calculating the Complex NBBO for a Complex Cross Order. The Exchange believes that the proposed additional calculations would address circumstances in which there is no NBB for a given leg or if there is displayed Customer interest on a given leg;

- either the Complex NBBO or the best-priced Complex Orders in the Consolidated Book is crossed (proposed Rule 6.62P–O(g)(2)(B));
- there is displayed Customer interest priced equal to the best-priced Complex Order(s) on either side of the market or both (the “best-priced complex interest”) and the Complex Cross Order price does not improve the best-priced complex interest by \$0.01 for the side(s) containing displayed Customer interest (proposed Rule 6.62P–O(g)(2)(C)); or
- there is no NBO for a given leg (proposed Rule 6.62P–O(g)(2)(D)).

This proposed rule text is designed to promote clarity and transparency in Exchange rules regarding the price requirements for a Complex Cross Order, including when there is no NBB or NBO on a given leg or there is displayed Customer interest equal to the best-priced complex interest and is designed to ensure that a Complex Cross Order would not trade ahead of displayed Customer interest.

¹⁰¹As described in the Complex Pillar Notice, *supra*, note 13, the Exchange has proposed to define the term “Complex NBBO” in proposed Rule 6.91P–O(a)(4) as “the derived national best bid and derived national best offer for a complex strategy calculated using the NBB and NBO for each component leg of a complex strategy.”

Proposed Rule 6.62P–O(g)(3) would define QCC Orders, which would be the only electronic Cross Orders available on Pillar at this time. As proposed, a QCC Order must be comprised of an originating order to buy or sell at least 1,000 contracts that is identified as being part of a qualified contingent trade coupled with a contra-side order or orders totaling an equal number of contracts. This proposed rule text is based on Rule 6.62–O(bb) with a non-substantive difference that the Pillar rule would not reference mini-options contracts, which no longer trade on the Exchange. Proposed Rule 6.62P–O(g)(3) would also specify that if a QCC has more than one option leg (a “Complex QCC Order”), each option leg must have at least 1,000 contracts, which is consistent with existing functionality. As described above, a Complex QCC Order must meet the requirements of proposed Rule 6.62P–O(g)(2) before it can be executed. In addition, Complex Cross Orders, including Complex QCCs, are available for options trading on other options exchanges, and therefore are not novel.¹⁰²

Proposed Rule 6.62P–O(g)(3)(A) and subparagraphs (i)–(vi) would define a “qualified contingent trade” as a transaction consisting of two or more component orders, executed as agent or principal, where specified requirements are also met and uses the same text as currently set forth in Commentary .02 and sub-paragraphs (a)–(f) to Rule 6.62–O without any differences.

Proposed Rule 6.62P–O(g)(3)(B) would specify rules governing QCC Orders entered from the Trading Floor, which can be entered only by Floor Brokers,¹⁰³ and is based on Commentary .01 to Rule 6.90–O without any substantive differences.¹⁰⁴ The

Exchange proposes textual changes as compared to the current Rule that are not designed to change the substance of the Rule, but to instead promote clarity and transparency. The proposed rule would provide that while on the Trading Floor, only Floor Brokers can enter QCC Orders and that Floor Brokers may not enter QCC Orders for their own account, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion (each a “prohibited account”). As further proposed, when executing such orders, Floor Brokers would not be subject to Rule 6.47–O regarding “Crossing” orders. Floor Brokers must maintain books and records demonstrating that each QCC Order entered from the Floor was not entered for a prohibited account. Any QCC Order entered from the Floor that does not have a corresponding record required by this paragraph would be deemed to have been entered for a prohibited account in violation of this Rule.

Proposed Rule 6.62P–O(g)(3)(C) would specify rules governing QCC Orders entered off-Floor and that OTP Holders must maintain books and records demonstrating that each such order was so routed. This proposed rule is based on Commentary .02 to Rule 6.90–O without any substantive differences.¹⁰⁵ The Exchange proposes textual differences as compared to the current Rule that are not designed to change the substance of the Rule, but instead promote clarity and transparency.

In connection with adding QCC to proposed Rule 6.62P–O, the Exchange proposes to add the following preamble to Rule 6.90–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.90–O would not be applicable to trading on Pillar.

Orders Available Only in Open Outcry. The Exchange proposes to add

entered for a prohibited account in violation of this Rule.”

¹⁰⁵ Commentary .02 to Rule 6.90–O provides: “With respect to a Qualified Contingent Cross Order that was routed to the NYSE Arca System from off of the Floor, OTP Holders must maintain books and records demonstrating that each such order was routed to the system from off of the Floor. This provision would not apply to a Qualified Contingent Cross Order covered by Commentary .01 to this NYSE Arca Rule 6.90–O (i.e., a Qualified Contingent Cross Order routed to a Floor Broker for entry into the NYSE Arca System).” The Exchange does not propose to include the last sentence of this Commentary in the proposed Pillar rule because the Exchange does not believe it is necessary to specify that Floor Brokers that enter orders electronically are subject to rules relating to electronic order entry as opposed to rules governing open outcry.

to Rule 6.62P–O(h) orders that are available only in open outcry, most of which are currently defined in Rule 6.62–O.

First, proposed Rule 6.62P–O(h)(1) would codify an existing order type, the Clear-the-Book (“CTB”) Order, which is currently described only in a Regulatory Bulletin.¹⁰⁶ The proposed definition would describe the CTB Order, which would be an order type available in open outcry that would interface with the Consolidated Book, and therefore with Pillar. As proposed, a CTB Order would be a Limit IOC Order that may be entered only by a Floor Broker, contemporaneous with executing an order in open outcry, that is approved by a Trading Official (the “TO Approval”). The CTB Order would be eligible to trade only with contra-side orders and quotes that were resting in the Consolidated Book prior to the TO Approval. In addition, proposed Rule 6.62P–O(h)(1)(A)–(C) would provide that:

- A CTB Order to buy (sell) would trade with contra-side orders and quotes with a display price below (above) the limit price of the CTB Order (proposed Rule 6.62P–O(h)(1)(A));

- A CTB Order to buy (sell) would trade with contra-side orders and quotes that have a display price and working price equal to the limit price of the CTB Order only if there is displayed Customer sell (buy) interest at that price, in which case, the CTB Order to buy (sell) would trade with the displayed Customer interest to sell (buy) and any non-Customer interest to sell (buy) with a working time earlier than the latest-arriving displayed Customer interest to sell (buy) (proposed Rule 6.62P–O(h)(1)(B)); and

- Any unexecuted portion of the CTB Order would cancel after trading with all better-priced interest and eligible same-priced interest on the Consolidated Book (proposed Rule 6.62P–O(h)(1)(C)).

Currently, CTB Orders only trade with displayed Customer interest and any same-priced displayed non-Customer interest ranked ahead of such interest in time priority, but do not trade with better-priced displayed non-Customer interest. In Pillar, per Rule 6.62P–O(h)(1)(B), CTB Orders would trade with displayed non-Customer interest priced better than the latest-arriving displayed Customer interest (i.e., a CTB order buying with a \$1.00 limit would

¹⁰² See, e.g., Cboe Rule 5.6(c) (setting forth operation of Complex QCC Orders) and Nasdaq ISE, LLC (“ISE”) Section 12(d) (same).

¹⁰³ An options Floor Broker is “an individual (either an OTP Holder or OTP Firm or a nominee of an OTP Holder or OTP Firm) who is registered with the Exchange for the purpose, while on the Exchange Floor, of accepting and executing option orders.” See Rule 6.43–O(a).

¹⁰⁴ Commentary .01 to Rule 6.90–O provides: “Qualified Contingent Cross Orders can be entered into the NYSE Arca System from on the Floor of the Exchange only by Floor Brokers. Floor Brokers shall not enter such orders for their own account, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion (each a ‘prohibited account’). When executing such orders, Floor Brokers shall not be subject to NYSE Arca Rule 6.47–O. Floor Brokers must maintain books and records demonstrating that each Qualified Contingent Cross Order entered from the Floor was not entered for a prohibited account. Any Qualified Contingent Cross Order entered from the Floor that does not have a corresponding record required by this Commentary .01 shall be deemed to have been

¹⁰⁶ See NYSE Arca Options RB–16–04, dated February 19, 2016 (Rules of Priority and Order Protection in Open Outcry), available here: <https://www.nyse.com/publicdocs/nyse/markets/arca-options/rule-interpretations/2016/NYSE%20Arca%20Options%20RB%2016-04.pdf>.

now trade with any displayed interest offered at \$0.99). Because Floor Brokers have an obligation to satisfy better-priced interest on the Consolidated Book, the Exchange believes this proposed change to automate such priority would make it easier for Floor Brokers to comply with Exchange priority rules. In addition, the Exchange believes that this proposed change would increase execution opportunities and achieve the goal of a CTB Order, which is to clear priority on the Consolidated Book at the time of the TO Approval.

In addition, proposed Rule 6.62P–O(h)(1)(D) would codify existing regulatory responsibilities of Floor Brokers utilizing CTB Orders to submit such orders in a timely manner after receiving TO Approval and would also provide that because CTB Orders are non-routable (and thus ineligible to clear Protected Quotations), Floor Brokers would still be obligated to route eligible orders to better-priced interest on Away Markets per Rule 6.94–O.¹⁰⁷

The Exchange also proposes to include in Rule 6.62P–O additional open outcry order types that are currently defined in Rule 6.62–O:

- Proposed Rule 6.62P–O(h)(2) would define “Facilitation Order” and is based on the Rule 6.62–O(j) definition of Facilitation Order without any differences.

- Proposed Rule 6.62P–O(h)(3) would define “Mid-Point Crossing Order” and is based on the Rule 6.62–O(q) definition of Mid-Point Crossing Order without any differences.

- Proposed Rule 6.62P–O(h)(4) would define “Not Held Order” and is based on the Rule 6.62–O(f) definition of Not Held Order without any differences.

- Proposed Rule 6.62P–O(h)(5) would define “Single Stock Future (“SSF”)/Option Order” and is based on the Rule 6.62–O(i) definition of Single Stock Future (“SSF”)/Option Order without any differences.

- Proposed Rule 6.62P–O(h)(6)(A) would define a “Stock/Option Order” and is based on the Rule 6.62–O(h)(1) definition of Stock/Option Order without any differences.

- Proposed Rule 6.62P–O(h)(6)(B) and subparagraphs (i) and (ii) would define a “Stock/Complex Order” and is based on the Rule 6.62–O(h)(2) definition of Stock/Complex Order with its subparagraphs without any differences.

The Exchange proposes that after the transition to Pillar, the following open outcry order types, which are currently described in Rule 6.62–O but are not used by Floor Brokers, would not be added to proposed Rule 6.62P–O governing orders and modifiers: One cancels the other (OCO) Order and Stock Contingency Order.

Additional Order Instructions and Modifiers. The Exchange proposes to specify the additional order instructions and modifiers that would be available in Pillar in proposed Rule 6.62P–O(i).

Proactive if Locked/Crossed Modifier. Proposed Rule 6.62P–O(i)(1) would provide that a Limit Order that is displayed and eligible to route and designated with a Proactive if Locked/Crossed Modifier would route to an Away Market if the Away Market locks or crosses the display price of the order and that if any quantity of the routed order is returned unexecuted, the order would be displayed in the Consolidated Book. This would be new functionality for options trading on the Exchange and is based on the Proactive if Locked/Crossed Modifier available on the Exchange’s cash equity platform, as described in Rule 7.31–E(i)(1) without any differences. The Exchange believes that offering this as an optional modifier for Limit Orders would provide OTP Holders and OTP Firms with additional flexibility to designate a resting displayed order to route if it becomes locked or crossed by an Away Market.

Self-Trade Prevention (“STP”) Modifier. Self-Trade Prevention (“STP”) Modifiers are currently defined in Commentary .01 to Rule 6.76A–O and are available only for Market Maker orders and quotes. On Pillar, the Exchange proposes to expand the availability of STP to all orders and quotes to offer this protection to trading interest of all OTP Holders and OTP Firms, not just Market Makers. The Exchange believes this expansion is appropriate because it would facilitate market participants’ compliance and risk management by assisting them in avoiding unintentional wash-sale trading. Because STP Modifiers are an instruction that can be added to an order or quote, the Exchange proposes that for Pillar, STP Modifiers would be described in proposed Rule 6.62P–O(i)(2). This is based on the structure of the Exchange’s cash equity rules, which also describe the STP Modifier in Rule 7.31–E(i), which is available to all market participants.

Proposed Rule 6.62P–O(i)(2) would provide that an Aggressing Order or Aggressing Quote to buy (sell) designated with one of the STP modifiers in proposed Rule 6.62P–

O(i)(2) would be prevented from trading with a resting order or quote to sell (buy) also designated with an STP modifier from the same MPID, and, if specified, any sub-identifier of that MPID and that the STP modifier on the Aggressing Order or Aggressing Quote would control the interaction between two orders and/or quotes marked with STP modifiers. In addition, STP would not be applicable during an Auction or to Cross Orders or when a Complex Order legs out. This proposed rule text is based on Commentary .01 to Rule 6.76A with non-substantive differences to use Pillar terminology.

Proposed Rule 6.62P–O(i)(2) would further provide that if the condition for a Limit Order designated FOK, an AON Order, or an arriving order with an MTS modifier designated under proposed Rule 6.62P–O(i)(3)(B)(i) (described below) cannot be met because of STP modifiers, such order would either be cancelled or placed on the Consolidated Book, as applicable. This functionality would be new on Pillar and reflects that for order types that must trade a specified quantity (either in full or a specified minimum quantity) and could trade with multiple contra-side orders to meet that size requirement, such order types would not be compatible with applying STP, which examines a one-on-one relationship between two interacting orders. This proposed rule text provides clarity that if a condition of an order cannot be met because of STP modifiers, the order would either cancel (*i.e.*, a Limit Order designated FOK), or be added to the Consolidated Book (*i.e.*, an AON Order or an order with an MTS modifier), and then such resting orders would function as described in Rule 6.62P–O.

The proposed rule would further provide that Aggressing Orders or Aggressing Quotes would be processed as follows:

- Proposed Rule 6.62P–O(i)(2)(A) would describe STP Cancel Newest (“STPN”) and provide that an Aggressing Order or Aggressing Quote to buy (sell) marked with the STPN modifier would not trade with resting interest to sell (buy) marked with any STP modifier from the same MPID; that the Aggressing Order or Aggressing Quote marked with the STPN modifier would be cancelled; and that the resting order or quote marked with one of the STP modifiers would remain on the Consolidated Book. This proposed rule is based on Commentary .01(a) to Rule 6.76A–O with non-substantive differences to use Pillar terminology.

- Proposed Rule 6.62P–O(i)(2)(B) would describe STP Cancel Oldest (“STPO”) and provide that an

¹⁰⁷ See *id.* at p. 2–3 (describing regulatory responsibilities related to CTB Orders, including that it is the Floor Broker’s responsibility to comply with the terms of the Options Order Protection and Locked/Crossed Market Plan, including by sending ISOs to trade with Protected Quotes).

Aggressing Order or Aggressing Quote to buy (sell) marked with the STPO modifier would not trade with resting interest to sell (buy) marked with any STP modifier from the same MPID; that the resting order or quote marked with the STP modifier would be cancelled; and that the Aggressing Order or Aggressing Quote marked with the STPO modifier would be placed on the Consolidated Book. This proposed rule is based on Commentary .01(b) to Rule 6.76A–O with non-substantive differences to use Pillar terminology.

- Proposed Rule 6.62P–O(i)(2)(C) would describe STP Cancel Both (“STPC”) and provide that an Aggressing Order or Aggressing Quote to buy (sell) marked with the STPC modifier would not trade with resting interest to sell (buy) marked with any STP modifier from the same MPID and that the entire size of both orders and/or quotes would be cancelled. This proposed rule is based on Commentary .01(c) to Rule 6.76A–O with non-substantive differences to use Pillar terminology.

Minimum Trade Size Modifier. The Exchange proposes to add the Minimum Trade Size (“MTS”) Modifier, which would be new functionality for options trading on Pillar that is based on the same functionality currently available for cash equity securities trading on Pillar, as described in Rule 7.31–E(i)(3). The Exchange proposes to provide this modifier for options trading to provide OTP Firms and OTP Holders with more features with respect to order handling. The proposed MTS Modifier is similar in concept to both FOK and AON, which are currently available for options trading. With the MTS Modifier, an OTP Holder or OTP Firm would have greater flexibility to designate a size smaller than the entire quantity (which is current FOK and AON functionality) as a condition for execution. The Exchange notes that the use of an MTS Modifier is not new or novel to options trading.¹⁰⁸ As with the MTS Modifier for cash equity trading, the proposed MTS Modifier for options traded on Pillar would be available only for non-displayed orders. Accordingly, proposed Rule 6.62P–O(i)(3) would provide that a Limit IOC Order or Non-Displayed Limit Order may be designated with an MTS Modifier.¹⁰⁹

¹⁰⁸ See, e.g., Nasdaq Options 3, Section 7(a)(3)(B) (describing “Minimum Quantity Order” as “an order that requires that a specified minimum quantity of contracts be obtained, or the order is cancelled”).

¹⁰⁹ For cash equity trading, the MTS Modifier is also available for an MPL Order or Tracking Order, which are non-displayed order types available on the Exchange’s cash equity trading platform that

Proposed Rule 6.62P–O(i)(3)(A) would provide that the quantity of the MTS Modifier may be less than the order quantity; however, an order would be rejected if it has an MTS Modifier quantity that is larger than the size of the order. This proposed rule is based on Rule 7.31–E(i)(3)(A) with differences only to reflect that the concept of a round lot is not applicable for options trading.

Proposed Rule 6.62P–O(i)(3)(B) would provide that one of the following instructions must be specified with respect to whether an order to buy (sell) with an MTS Modifier would trade on arrival with: (i) Orders or quotes to sell (buy) in the Consolidated Book that in the aggregate meet such order’s MTS; or (ii) only individual order(s) or quote(s) to sell (buy) in the Consolidated Book that each meets such order’s MTS. This proposed rule is based on Rule 7.31–E(i)(3)(B) and sub-paragraphs (i) and (ii) with only non-substantive differences to use options trading terminology (e.g., Consolidated Book instead of NYSE Arca Book and reference to quotes). Otherwise, the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(C) would provide that an order with an MTS Modifier that is designated Day or GTC that cannot be executed immediately on arrival would not trade and would be ranked in the Consolidated Book. In such case, the order to buy (sell) with an MTS Modifier to buy (sell) that is ranked in the Consolidated Book would not be eligible to trade: (i) At a price equal to or above (below) any orders or quotes to sell (buy) that are displayed at a price equal to or below (above) the working price of such order with an MTS Modifier; or (ii) at a price above (below) any orders or quotes to sell (buy) that are not displayed and that have a working price below (above) the working price of such order with an MTS Modifier. This proposed rule is based on Rule 7.31–E(i)(3)(C) and sub-paragraphs (i) and (ii) with only non-substantive differences to use options trading terminology and to reflect the availability of the GTC time-in-force modifier for Non-Displayed Limit Orders. Otherwise, the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(D) would provide that an order with an MTS Modifier that is designated IOC and cannot be immediately executed would be cancelled. This proposed rule is based on Rule 7.31–E(i)(3)(D) without

would not be available for options trading on Pillar. See Rule 7.31–E(i)(3).

any differences and the functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(E) would provide that a resting order to buy (sell) with an MTS Modifier would trade with individual orders and quotes to sell (buy) that each meet the MTS and that (i) if an Aggressing Order or Aggressing Quote to sell (buy) does not meet the MTS of the resting order to buy (sell) with an MTS Modifier, that Aggressing Order or Aggressing Quote would not trade with, and may trade, through such resting order with an MTS Modifier; and (ii) if a resting non-displayed order or quote to sell (buy) did not meet the MTS of a same-priced resting order or quote to buy (sell) with an MTS Modifier, a subsequently arriving order or quote to sell (buy) that meets the MTS would trade before such resting non-displayed order or quote to sell (buy) at that price. This proposed rule is based on Rule 7.31–E(i)(3)(E) and sub-paragraphs (i) and (ii) with only non-substantive differences to use options trading terminology (i.e., refers to an order trading with contra-side quotes). Otherwise, the proposed functionality would be identical on both the options and cash equity trading platforms.

Proposed Rule 6.62P–O(i)(3)(F) would provide that a resting order with an MTS Modifier would be cancelled if it is traded in part or reduced in size and the remaining quantity is less than such order’s MTS. This proposed rule is based on Rule 7.31–E(i)(3)(F) without any differences and the functionality would be identical on both the options and cash equity trading platforms.

In connection with proposed Rule 6.62P–O, the Exchange proposes to add the following preamble to Rule 6.62–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.62–O would not be applicable to trading on Pillar.

Proposed Rule 6.37AP–O: Market Maker Quotations

Current Rule 6.37A–O describes Market Maker quoting obligations, including defining “quotations,” describing the treatment of such quotations, and specifying Market Maker and LMM quoting obligations. Proposed Rule 6.37AP–O would set forth Market Maker quoting obligations under Pillar.

As with current functionality, on Pillar, the Exchange would provide Market Makers with the ability to designate bids and offers as quotations, which is unique to options trading and not applicable to cash equity trading.

Currently, the Exchange offers designated “quotation” types to Market Makers, which are described in Rule 6.37A–O(a)(3).¹¹⁰ With Pillar, the Exchange is proposing to modify how a Market Maker would be able to send bids and offers as quotations and would no longer need to offer distinct “quotation” types to identify Market Maker quotations. Instead, and as discussed in more detail below, with Pillar, the Exchange proposes that Market Makers would be able to designate specified “order” types as quotations. If designated as a quotation, such bids and offers would be displayed, traded, repriced, or cancelled as described in proposed Rule 6.62P–O(e), discussed above. In addition, if designated as a quotation, such bids or offers would be identifiable to the Exchange as “quotations,” subject to the Market Maker and LMM requirements relating to quotations. If a Market Maker does not choose to designate a bid or offer as a quotation, such bid or offer would be processed as an “order” rather than as a “quote.”¹¹¹

- Rule 6.37AP–O(a) would be based on current Rule 6.37A–O(a) and would provide that a Market Maker may send quotations only in the issues included in its appointment. This functionality would not be new and the Exchange proposes one difference from the current Rule to use the term “send” rather than “enter.”

- Proposed Rule 6.37AP–O(a)(1) would provide that the term “quote” or “quotation” means “a bid or offer sent by a Market Maker that is not sent as an order” and that “[o]nce received by the Exchange, a subsequent quotation sent by a Market Maker replaces that Market Maker’s previously displayed same-side quotation.” This proposed Rule is similar to current Rule 6.37A–O(a)(1), which provides that “[t]he term ‘quote’ or ‘quotation’ means a bid or offer entered by a Market Maker that updates the Market Maker’s previous bid or offer, if any.” The Exchange proposes

¹¹⁰ As described in Rule 6.37A–O(a)(3)(A)–(C), a Market Maker may designate a quote as Market Maker–Light Only Quotation (“MMLO”), Market Maker–Add Liquidity Only Quotation (“MMALO”), and Market Maker–Repricing Quotation (“MMRP”).

¹¹¹ For example, a Market Maker could choose to designate a Non-Routable Limit Order as either a quote or as an order, which is consistent with current Rule 6.37B–O, which provides that a Market Maker may enter all order types permitted to be entered by Users under the Rules to buy or sell options in all classes of options listed on the Exchange. Accordingly, the proposed Rule is not materially different for Market Makers because they currently can choose to send as Market Maker orders the order types described in current Rule 6.62–O, including, for example, RPNP, RALO, PNP–Blind Order, and PNP Light Order.

textual differences to use the terms “sent” and “received” instead of “entered.” In addition, because of the proposed Pillar implementation regarding how a Market Maker may designate a quote (*i.e.*, as a Non-Routable Limit Order or ALO Order as described herein and below), the Exchange proposes a difference from the current Rule to provide that a quote is a bid or offer not designated as an order. The second sentence of proposed Rule 6.37A–O(a)(1) would provide greater granularity and make clear that the Exchange would accept multiple quotations from a Market Maker and that any subsequent quote would cancel an existing displayed same-side quote. This proposed text is consistent with the current Rule, which provides that a Market Maker quotation updates a Market Marker’s previous bid or offer.

- Proposed Rule 6.37AP–O(a)(2) would provide that a Market Maker may designate either a Non-Routable Limit Order or an ALO Order as a quote and such quotes would be processed as described in proposed Rule 6.62P–O.¹¹² On Pillar, the Exchange would not offer the existing quote types (*i.e.*, MMLO, MMALO and MMRP). Because proposed Rule 6.62P–O(e)(1) and (2), described above, would set forth the treatment of a Non-Routable Limit Order or an ALO Order designated as a quote, the Exchange will not include a (duplicative) section in proposed Rule 6.37AP–O regarding the treatment of such quotes. As noted above regarding proposed Rule 6.62P–O(e), the Exchange believes that allowing quotes to be designated as one of two orders types (*i.e.*, Non-Routable Limit or ALO) would streamline the rules by consolidating into one rule the description of the proposed quote/order behavior and therefore obviate the need to separately describe the same functionality in two rules.

- Proposed Rule 6.37AP–O(b)–(e) would be substantively identical to current Rule 6.37A–O(b)–(e) with non-substantive differences to change the term “shall” to “will,” which is a stylistic preference that would add consistency to Exchange rules. Proposed Commentary .01 to Rule 6.37AP–O would be substantively identical to Commentary .01 to Rule 6.37A–O, with non-substantive differences to streamline the rule text.

The Exchange also proposes a non-substantive change to paragraph (b) of

¹¹² See discussion *supra* regarding proposed Rule 6.62P–O(e)(1) and (2), Non-Routable Limit Order and ALO Orders, respectively, being available as quote types and how such orders compare to the existing MMLO, MMRP, and MMALO quotation functionality.

Rule 6.65A–O (Limit-Up and Limit-Down During Extraordinary Market Volatility) to correct a cross reference to Market Maker quoting obligations as set forth in Rule 6.37AP–O(b) and (c). Current Rule 6.65A(b) erroneously cross-references Rule 6.37B–O(b) and (c).

In connection with proposed Rule 6.37AP–O, the Exchange proposes to add the following preamble to Rule 6.37A–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.37A–O would not be applicable to trading on Pillar.

Proposed Rule 6.40P–O: Pre-Trade and Activity-Based Risk Controls

For the OX system, current Rule 6.40–O sets forth the activity-based Risk Limitation Mechanisms for orders and quotes, which are designed to help OTP Holders and OTP Firms effectively manage risk during periods of increased and significant trading activity. With the transition to Pillar, the Exchange proposes to incorporate new risk control functionality that is based on both existing activity-based risk controls for options and pre-trade risk controls that are available on the Exchange’s cash equity platform. Proposed Rule 6.40P–O would describe the activity-based controls with updated functionality under Pillar and would also describe new optional pre-trade risk controls that are based on pre-trade risk controls available on the Exchange’s cash equity platform, as described in Rule 7.19–E, with proposed differences to reference quotes and proposed new Pillar functionality. The Exchange believes that adding pre-trade risk controls (together with the enhanced activity-based controls) for options trading, as described below, would provide greater flexibility to OTP Holders and OTP Firms in establishing risk controls to align with their risk tolerance for both orders and quotes.

Proposed Rule 6.40P–O(a) would set forth the following definitions that would be used for purposes of the Rule:

- The term “Entering Firm” would mean an OTP Holder or OTP Firm (including those acting as Market Makers) (proposed Rule 6.40P–O(a)(1)). This proposed definition is based in part on the definition of “Entering Firm” in Rule 7.19–E(a)(1) and the Exchange believes that the addition of this term would add clarity to the proposed rule by using a single, defined term to describe which entities, including Market Makers, could avail themselves of the proposed pre-trade risk controls.

• The term “Pre-Trade Risk Controls” would refer to two optional limits that an Entering Firm may utilize with respect to its trading activity on the Exchange (proposed Rule 6.40P–O(a)(2)). These controls would be the “Single Order Maximum Notional Value Risk Limit” and the “Single Order Maximum Quantity Risk Limit.” The proposed Pre-Trade Controls are based on the substantially identical risk controls available on the Exchange’s cash equity market, as described in Rules 7.19–E(a)(3) and (4), respectively, but differ in that the proposed rule would also apply to quotes, which are unique to options trading, and specifies the treatment of orders designated GTC, which are available for options trading but are not offered on the Exchange’s cash equity market.

○ The term “Single Order Maximum Notional Value Risk Limit” would refer to a pre-established maximum dollar amount for a single order or quote to be applied one time (proposed Rule 6.40P–O(a)(2)(A)). This definition would also provide that orders designated GTC would be subject to this pre-trade risk control only once.

○ The term “Single Order Maximum Quantity Risk Limit” would refer to a pre-established maximum number of contracts that may be included in a single order or quote before it can be traded (proposed Rule 6.40P–O(a)(2)(B)). This definition would also provide that orders designated GTC would be subject to this pre-trade risk control only once.

• The term “Activity-Based Risk Controls” would refer to three activity-based risk limits that an Entering Firm may apply to its orders and quotes in an options class based on specified thresholds measured over the course of an Interval (to be defined below) (proposed Rule 6.40P–O(a)(3)). The proposed Activity-Based Risk Controls are based on the substantially identical risk controls set forth in current Rule 6.40–O(b)–(d), except that on Pillar, a Market Maker’s orders and quotes would be aggregated and applied towards each risk limit (as opposed to current functionality, where a Market Maker’s orders and quotes are counted separately). The Exchange believes that aggregating a Market Maker’s quotes and orders for purposes of calculating activity-based risk controls would better reflect the aggregate risk that a Market Maker has with respect to its quotes and orders.

○ The term “Transaction-Based Risk Limit” would refer to a pre-established limit on the number of an Entering Firm’s orders and quotes executed in a specified class of options per Interval

(proposed Rule 6.40P–O(a)(3)(A)). This risk control is based on the substantially identical risk control set forth in current Rule 6.40–O(b), with the difference described above that a Market Maker’s orders and quotes would be aggregated.

○ The term “Volume-Based Risk Limit” would refer to a pre-established limit on the number of contracts of an Entering Firm’s orders and quotes that could be executed in a specified class of options per Interval (proposed Rule 6.40P–O(a)(3)(B)). This risk control is based on the substantially identical risk control set forth in current Rule 6.40–O(c), with the difference described above that a Market Maker’s orders and quotes would be aggregated.

○ The term “Percentage-Based Risk Limit” would refer to a pre-established limit on the percentage of contracts executed in a specified class of options as measured against the full size of such Entering Firm’s orders and quotes executed per Interval (proposed Rule 6.40P–O(a)(3)(C)). The proposed definition would also provide that to determine whether an Entering Firm has breached the specified percentage limit, the Exchange would calculate the percent of each order or quote in a specified class of option that is executed during an Interval (each, a “percentage”), and sum up those percentages. As further proposed, this definition would state that this risk limit would be breached if the sum of the percentages exceeds the pre-established limit. This risk control is based on the substantially identical risk control set forth in current Rule 6.40–O(d), with the difference described above that a Market Maker’s orders and quotes would be aggregated.

• The term “Global Risk Control” would refer to a pre-established limit on the number of times an Entering Firm may breach its Activity-Based Risk Controls per Interval (proposed Rule 6.40P–O(a)(4)). This proposed definition is based on the substantially identical functionality set forth in current Rule 6.40–O(f).

• The term “Interval” would refer to the configurable time period during which the Exchange would determine if an Activity-Based Risk Control or the Global Risk Control has been breached (proposed Rule 6.40P–O(a)(5)). This proposed definition is consistent with current Rule 6.40–O, which contains references throughout to a “time period” during which the Exchange will determine whether a breach has occurred. The Exchange believes this proposed definition would add clarity and transparency to Exchange rules.

Proposed Rule 6.40P–O(b) would set forth how the Pre-Trade, Activity-Based

and Global Risk Controls could be set or adjusted. Proposed Rule 6.40P–O(b)(1) would provide that these risk controls may be set before the beginning of a trading day and may be adjusted during the trading day. Proposed Rule 6.40P–O(b)(2) would provide that Entering Firms may set these risk controls at the MPID level or at one or more sub-IDs associated with that MPID, or both. Proposed Rule 6.40P–O(b) is based on Rule 7.19–E(b)(3)(A)–(B) but differs in that the proposed rule would incorporate the existing options-based Activity-Based and Global Risk Controls in addition to the (new for options trading) Pre-Trade Risk Controls currently available on the Exchange’s cash equity platform. The Exchange notes that the Activity-Based and Global Risk Controls are unique to the options market and, at this time, the Exchange’s cash equities platform does not offer analogous controls.

Proposed Rule 6.40P–O(c) would set forth the Automated Breach Actions that the Exchange would take if a designated risk limit is breached. Proposed Rule 6.40P–O(c)(1)(A)(i)–(ii) would set forth the automated breach actions for the Pre-Trade Risk Controls.

• Proposed Rule 6.40P–O(c)(1)(A)(i) would provide that a Limit Order or quote that breaches the designated limit of either a Single Order Maximum Notional Value Risk Limit or Single Order Maximum Quantity Risk Limit would be rejected.

• Proposed Rule 6.40P–O(c)(1)(A)(ii) would provide that a Market Order that breaches the designated limit of a Single Order Maximum Quantity Risk Limit would be rejected. The proposed rule would also provide that a Market Order that breaches the designated limit of a Single Order Notional Value Risk Limit would be rejected if the order arrived during continuous trading or canceled if the order was received during a pre-open state and the quantity remaining to trade after an Auction concludes breaches the designated limit.¹¹³

Proposed Rule 6.40P–O(c)(1)(A)(i)–(ii) is based on Rule 7.19–E(c)(2) but differs in that it specifies the treatment of Limit Orders and Market Orders (the latter having different treatment based on when such orders arrive at the Exchange) and expands application of the check to include quotes. The Exchange proposes to process Market Orders differently because, until a series is opened, the Exchange is not able to calculate the Single Order Notional

¹¹³ The term “Auction” is defined in proposed Rule 6.64P–O(a)(1), described below in the discussion of proposed Rule 6.64P–O, to mean the opening or reopening of a series for trading either on a trade or quote.

Value Risk Limit for a Market Order. Accordingly, this risk limit would be applied only after a series opens, at which point, a Market Order would be cancelled if it fails the risk limit.

Proposed Rule 6.40P–O(c)(2) would set forth the automated breach actions for the Activity-Based Risk Controls.

- Proposed Rule 6.40P–O(c)(2)(A) would first specify that an Entering Firm acting as a Market Maker would be required to apply one of the Activity-Based Risk Controls to all of its orders and quotes; whereas an Entering Firm that is not acting as a Market Maker would have the option, but would not be required, to apply one of the Activity-Based Risk Controls to its orders. The requirement that Market Makers utilize Activity-Based Risk Controls for all quotes mirrors the requirements set forth in Rule 6.40–O, Commentary .04(a); however, the proposed rule differs in that it likewise requires Market Makers to apply one of the Activity-Based Risk Controls to all of its orders. The Exchange believes that requiring that both Market Maker quotes and Market Maker orders be subject to one of the Activity-Based Controls would enhance Market Makers' ability to assess their total risk exposure on the Exchange. The proposed optionality of the Activity-Based Risk controls for orders sent by an Entering Firm not acting as a Market Maker mirrors current Rule 6.40–O, Commentary .04(b)).

- Proposed Rule 6.40P–O(c)(2)(B) would provide that to determine when an Activity-Based Risk Control has been breached, the Exchange would maintain Trade Counters that would be incremented every time an order or quote trades, including any leg of a Complex Order, and would aggregate the number of contracts traded during each such execution. As further proposed, an Entering Firm may opt to exclude any orders designated IOC or FOK from being considered by a Trade Counter. This is consistent with existing functionality set forth in Rule 6.40–O(a) and Commentary .07, with a proposed difference to allow an Entering Firm to also exclude orders designated FOK, which, like orders designated IOC, cancel if not executed on arrival and is based on current functionality.¹¹⁴ The Exchange believes that specifying that

orders designated FOK could be excluded from being considered for a Trade Counter would add granularity and clarity to Exchange rules. In addition, as noted above, a Market Maker's quotes and orders in a given option class would be aggregated and therefore the Exchange proposes that there would not be separate Trade Counters for a Market Maker's quotes and orders.

- Proposed Rule 6.40P–O(c)(2)(C) would provide that each Entering Firm must select one of three Automated Breach Actions for the Exchange to take should the Entering Firm breach an Activity-Based Risk Control.

- “Notification Only.” As set forth in proposed Rule 6.40P–O(c)(2)(C)(i), if this option is selected, the Exchange would continue to accept new order and quote messages and related instructions and would not cancel any unexecuted orders or quotes in the Consolidated Book. With the “Notification Only” action, the Exchange would provide such notifications, but would not take any other automated actions with respect to new or unexecuted orders. This proposed functionality is not currently available for options trading, but is available for breach of the Gross Credit Risk Limit on the Exchange's cash equity platform, as set forth in Rule 7.19–E(c)(3)(A)(i). The Exchange believes that making this Automated Breach Action available to Activity-Based Risk Controls, which are unique to options trading, would provide Entering Firms more control and flexibility over setting risk tolerance and, as such, over how Activity-Based Risk Controls are implemented.

- “Block Only.” As set forth in proposed Rule 6.40P–O(c)(2)(C)(ii), if this option is selected, the Exchange would reject new order and quote messages and related instructions, provided that the Exchange would continue to process instructions from the Entering Firm to cancel one or more orders or quotes (including Auction-Only Orders) in full. The proposed rule would also provide that the Exchange would follow any instructions specified in paragraph (e) of the proposed Rule (and described below). This proposed functionality is not currently available for options trading under current Rule 6.40–O, but is available for breach of the Gross Credit Risk Limit on the Exchange's cash equity platform, as set forth in Rule 7.19–E(c)(3)(A)(ii). The Exchange believes that making this Automated Breach Action available to Activity-Based Risk Controls, which are unique to options trading, would provide Entering Firms more control and flexibility over setting risk tolerance

and, as such, over how Activity-Based Risk Controls are implemented.

- “Cancel and Block.” As set forth in proposed Rule 6.40P–O(c)(2)(C)(iii), if this option is selected, in addition to the Block actions described above, the Exchange would also cancel all unexecuted orders and quotes in the Consolidated Book other than Auction-Only Orders and orders designated GTC. This proposed Cancel and Block functionality is substantially similar to the automated breach action taken by the Exchange per current Rule 6.40–O(e) and Commentaries .01 and .02 thereto, except that under the current rules, this is default (not optional) functionality. Additionally, this proposed functionality is substantially identical to the Cancel and Block option set forth in Rule 7.19–E(c)(3)(A)(iii), which is available for breach of the Gross Credit Risk Limit on the Exchange's cash equity platform. The Exchange believes that making this Automated Breach Action available to respond to a breach of Activity-Based Risk Controls, which are unique to options trading, would provide Entering Firms more control and flexibility over setting risk tolerance and, as such, over how Activity-Based Risk Controls are implemented.

- Finally, proposed Rule 6.40P–O(c)(2)(D) would provide that if an Entering Firm breaches an Activity-Based Risk Control, the Automated Breach Action selected would be applied to its orders and quotes in the affected class of options. This proposed action is consistent with current Rule 6.40–O(e) and Commentaries .01 and .02 thereto, which provide that, upon a breach, the Exchange will cancel existing and suspend new orders and quotes trading in the affected class.

Proposed Rule 6.40P–O(c)(2)(E) would provide that the Exchange would specify by Trader Update any applicable minimum, maximum and/or default settings for the Activity-Based Risk Controls, subject to the following:

- For the Transaction-Based Risk Limit, the minimum setting would not be less than one and the maximum setting would not be more than 2,000 (proposed Rule 6.40P–O(c)(2)(E)(i)), which settings are identical to the Exchange-determined settings provided under current Rule 6.40–O, Commentary .03.

- For the Volume-Based Risk Limit, the minimum setting would not be less than one and the maximum setting would not be more than 500,000 (proposed Rule 6.40P–O(c)(2)(E)(ii)), which settings are identical to the Exchange-determined settings provided under current Rule 6.40–O, Commentary .03.

¹¹⁴ See Securities Exchange Act Release No. 81717 (September 25, 2017), 82 FR 45631 (September 29, 2017) (SR–NYSEArca–2017–96) (immediately effective filing to exclude IOC Orders from risk settings because such exclusion, among other things, would result in risk settings that may be better calibrated to suit the needs of certain market participants (*i.e.*, those that routinely utilize IOC orders to access liquidity on the Exchange)).

- For the Percentage-Based Risk Limit, the minimum setting would not be less than 50 and the maximum setting would not be more than 200,000 (proposed Rule 6.40P–O(c)(2)(E)(iii)), which maximum setting is the same as the minimum Exchange-determined setting set forth in current Rule 6.40–O, Commentary .03. The Exchange proposes to increase the minimum setting from less than one (in current rule) to not be less than 50 to better reflect actual practice, because under current Rules, there are no OTP Holders or OTP Firms that have set their Percentage-Based Risk Limits below 50.

Proposed Rule 6.40P–O(c)(2)(F) would provide that the Exchange would specify by Trader Update the Interval for the Activity-Based Risk Controls, subject to the following:

- The Interval would not be less than 100 milliseconds and would not be greater than 300,000 milliseconds, inclusive of the duration of any trading halt occurring within that time (proposed Rule 6.40P–O(c)(2)(F)(i)), which minimum setting is identical to the Exchange-determined minimum set forth in current Rule 6.40–O, Commentary .03. Although the current rule does not include a maximum time period, the Exchange proposes to include a maximum allowable Interval to promote clarity in Exchange rules of the longest time an Interval could be.

- For transactions occurring in the Core Open Auction, per Rule 6.64P–O, the applicable time period would be the lesser of (i) the time between the Core Open Auction of a series and the initial transaction or (ii) the Interval (proposed Rule 6.40P–O(c)(2)(F)(ii)), which proposed time period is identical to the timing provided under current Rule 6.40–O, Commentary .03.

Proposed Rule 6.40P–O(c)(3) would set forth the automated breach actions for the Global Risk Controls set by an Entering Firm.

- Proposed Rule 6.40P–O(c)(3)(A) would provide that if the Global Risk Control limit is breached, the Exchange would Cancel and Block, per proposed Rule 6.40P(c)(2)(C)(iii), which proposed functionality is substantively the same as the functionality provided under current Rule 6.40–O, Commentaries .01 (regarding cancellation of existing orders) and .02 (regarding block/rejection of new orders).

- Proposed Rule 6.40P–O(c)(3)(B) would provide that if an Entering Firm breaches the Global Risk Control, the Automated Breach Action would be applied to all orders and quotes of the Entering Firm in all classes of options regardless of which class(es) of options caused the underlying breach of

Activity-Based Risk Controls, which proposed functionality is substantively the same as the functionality provided (in the last sentence) of current Rule 6.40–O, Commentary .02 in the event of a breach of current Rule 6.40–O(f) (*i.e.*, breach of global risk setting).

- Proposed Rule 6.40P–O(c)(3)(C) would provide that the Exchange would specify by Trader Update any applicable minimum, maximum and/or default settings for the Global Risk Controls, provided that the minimum setting would not be less than 25 and the maximum setting would not be more than 100. These proposed settings are based on the Exchange-determined setting provided under current rule 6.40–O, Commentary .03, except that the current rule allows for a minimum setting of one (1) whereas the proposed rule is increasing that minimum to twenty-five (25), which the Exchange believes would better reflect actual practice, because under current Rules, there are no OTP Holders or OTP Firms that have set their Global Risk Controls below 25.

- Proposed Rule 6.40P–O(c)(3)(D) would provide that the Exchange would specify by Trader Update the Interval for the Global Risk Controls, subject to the following:

- The Interval would not be less than 100 milliseconds and would not be greater than 300,000 milliseconds, inclusive of the duration of any trading halt occurring within that time, per proposed Rule 6.40P–O(c)(3)(D)(i), which minimum setting is identical to the Exchange-determined minimum set forth in current Rule 6.40–O, Commentary .03. Although the current rule does not include a maximum time period, the Exchange proposes to include a maximum allowable Interval to allow an outside parameter by which the counters would be reset, which would promote transparency in Exchange rules regarding the maximum allowable Interval.

- For transactions occurring in the Core Open Auction, per Rule 6.64P–O, the applicable time period is the lesser of (i) the time between the Core Open Auction of a series and the initial transaction or (ii) the Interval, per proposed Rule 6.40P–O(c)(3)(D)(ii), which proposed time period is identical to the timing provided under current Rule 6.40–O, Commentary .03.

Proposed Rule 6.40P–O(d) describes how an Entering Firm's ability to enter orders, quotes, and related instructions would be reinstated after a "Block Only" or "Cancel and Block" Automated Breach Action has been triggered. In such case, proposed Rule 6.40P–O(d) provides that the Exchange

would not reinstate the Entering Firm's ability to enter orders and quotes and related instructions on the Exchange (other than instructions to cancel one or more orders or quotes (including Auction-Only Orders and orders designated GTC) in full) without the consent of the Entering Firm, which may be provided via automated contact if it was a breach of an Activity-Based Risk Control. As further proposed, an Entering Firm that breaches the Global Risk Control would not be reinstated unless the Entering Firm provides consent via non-automated contact with the Exchange. This proposed functionality is consistent with current Rule 6.40–O, Commentary .02 regarding the need for an Entering Firm to make automated or non-automated contact with the Exchange, as applicable, prior to being reinstated. Proposed Rule 6.40P–O(d) is also substantively the same as the more granular level of risk control under Pillar functionality available for cash equity trading per Rule 7.19–E(d), except that the proposed rule does not reference Clearing Firms, which feature would remain specific to cash-equity trading and not be applied to options trading.

Proposed Rule 6.40P–O(e) would set forth new "Kill Switch Action" functionality, which would allow an Entering Firm to direct the Exchange to take certain bulk cancel or block actions with respect to orders and quotes. In contrast to the Automated Breach Actions described above, which the Exchange would take automatically after the breach of a risk limit, the Exchange would not take any of the Kill Switch Actions without express direction from an Entering Firm. The Exchange believes that the proposed Kill Switch Action functionality would also provide OTP Holders and OTP Firms with greater flexibility to provide bulk instructions to the Exchange with respect to cancelling existing orders and quotes and blocking new orders and quotes.

Proposed Rule 6.40P–O(e) would specify that an Entering Firm could direct the Exchange to take one or more of the following actions with respect to orders and quotes at either an MPID, or if designated, sub-ID Level: (1) Cancel all Auction-Only Orders; (2) Cancel all orders designated GTC; (3) Cancel all unexecuted orders and quotes in the Consolidated Book other than Auction-Only Orders and orders designated GTC; or (4) Block the entry of any new order and quote messages and related instructions, provided that the Exchange would continue to accept instructions from Entering Firms to cancel one or more orders or quotes (including

Auction-Only Orders and orders designated GTC) in full, and later, reverse that block. The proposed post-trade Kill Switch Actions are not currently available for options trading per Rule 6.40–O and are substantially identical to the Kill Switch Action available on the Exchange’s cash equity platform pursuant to Rule 7.19–E(e), with a difference to address the handling of quotes as well as orders designated GTC, which are not available on the cash equity platform. The Exchange believes that offering this functionality for options trading under Pillar would give Entering Firms more flexibility in setting risk controls for options trading (as noted above) and add consistency with the Exchange’s risk control functionality available for cash equity trading. Providing “Kill Switch Action” functionality in Exchange rules is consistent with the rules of other options exchanges.¹¹⁵

Proposed Commentary .01 to Rule 6.40P–O would provide that the Pre-Trade, Activity-Based, and Global Risk Controls described in the proposed Rule 6.40P–O are meant to supplement, and not replace, the OTP Holder’s or OTP Firm’s own internal systems, monitoring, and procedures related to risk management and are not designed for compliance with Rule 15c3–5 under the Exchange Act.¹¹⁶ Responsibility for compliance with all Exchange and SEC rules remains with the OTP Holder or OTP Firm. This proposed language is not included in existing Rule 6.40–O, and is based on Commentary .01 to Rule 7.19–E. The proposed rule makes clear that use of the proposed controls alone does not constitute compliance with Exchange rules or the Exchange Act.

In connection with proposed Rule 6.40P–O, the Exchange proposes to add the following preamble to Rule 6.40–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.40–O would not be applicable to trading on Pillar.

Proposed Rule 6.41P–O: Price Reasonability Checks—Orders and Quotes

The Exchange proposes to describe its Price Reasonability Checks for orders and quotes in proposed Rule 6.41P–

O.¹¹⁷ For the OX system, the concept of “Price Reasonability Checks” for Limit Orders are described in Rule 6.60–O(c) and the concept of price protection filters for quotes are described in Rule 6.61–O. The proposed “Price Reasonability Checks” on Pillar would be applicable to both orders and quotes and are designed to provide similar price protections as the current price checks for Limit Orders on the OX system, with differences as described in more detail below. The Exchange believes that applying the same Price Reasonability Checks to both orders and quotes and describing them in a single rule would make the Exchange’s rules easier to navigate. The Exchange proposes to locate the rule text for the proposed Price Reasonability Checks in Rule 6.41P–O to immediately follow Rule 6.40P–O regarding the Pre-Trade and Activity-Based Controls, as this placement would group the risk controls together and make Exchange rules easier to navigate.

Proposed Rule 6.41P–O(a)(1)–(3) would set forth the circumstances under which the proposed Price Reasonability Checks would apply. Proposed Rule 6.41P–O(a) would provide that the Exchange would apply the Price Reasonability Checks, as defined in proposed paragraphs (b) and (c), to all Limit Orders and quotes (excluding those represented in open outcry), during continuous trading on each trading day, subject to the following:

- Proposed Rule 6.41P–O(a)(1) would provide that a Limit Order or quote received during a pre-open state would be subject to the proposed Price Reasonability Checks after an Auction concludes; that a Limit Order or quote that was resting on the Consolidated Book before a trading halt would be subject to the proposed Price Reasonability Checks again after the Trading Halt Auction; and that a put option message to buy would be subject to the Arbitrage Check regardless of when it arrives. This proposed rule is based on current Rule 6.60–O(c), which provides that the Price Reasonability Checks (for orders) are applied when a series opens or reopens for trading. Proposed Rule 6.41P–O(a)(1) includes additional detail and granularity regarding when the proposed Price Reasonability Checks would be applied under Pillar. The proposed Rule also adds new functionality that a put option message to buy would be subject to the Arbitrage Check even if a series is not

open for trading. The Exchange believes that it is appropriate to apply this check to put option messages to buy at any time because the check is not dependent on an external reference price.

- Proposed Rule 6.41P–O(a)(2) would provide that if the calculation of the Price Reasonability Check is not consistent with the MPV for the series, it would be rounded down to the nearest price within the applicable MPV, which is consistent with current functionality. The Exchange believes this proposed rule would promote clarity and transparency in Exchange rules regarding how the Price Reasonability Check would be calculated.

- Proposed Rule 6.41P–O(a)(3) would provide that the proposed Price Reasonability Checks would not apply to (i) any options series for which the underlying security has a non-standard cash or stock deliverable as part of a corporate action; (ii) any options series for which the underlying security is identified as over-the-counter (“OTC”); (iii) any option series on an index; and (iv) any option series for which the Exchange determines it is necessary to exclude underlying securities in the interests of maintaining a fair and orderly market, which the Exchange would announce by Trader Update. Proposed Rule 6.41P–O(a)(3) is based on current Commentary .01 to Rule 6.60–O (orders) and 6.61–O (quotes), with a non-substantive difference that the proposed rule no longer references Binary Return Derivatives (“ByRDs”) because ByRDs are no longer traded on the Exchange.

Proposed Rule 6.41P–O(b) would set forth the “Arbitrage Checks” for buy orders or quotes, which subset of Price Reasonability Checks are based on the principle that an option order is in error and should be rejected (or canceled) when the same result can be achieved on the market for the underlying equity security at a lesser cost.

- Proposed Rule 6.41P–O(b)(1) relates to “puts” and would provide that order or quote messages to buy for put options would be rejected if the price of the order or quote is equal to or greater than the strike price of the option, which is substantively identical to current Rule 6.60–O(c)(1)(A) for orders, with a proposed difference that proposed “Arbitrage Check” would also apply to quotes.

- Proposed Rule 6.41P–O(b)(2) relates to “calls” and would provide that order or quote messages to buy for call options would be rejected or canceled (if resting) if the price of the order or quote is equal to or greater than the last sale price of the underlying security on the

¹¹⁵ See, e.g., Cboe Rule 5.34(c)(6) (describing the optional “Kill Switch” functionality, which allows a Cboe participant to instruct Cboe to simultaneously cancel or reject all orders or quotes (or a subset thereof) as well as to instruct Cboe to block all orders or quotes (or a subset thereof), which block instructions will remain in effect until such participant contacts Cboe’s trade desk to remove the block).

¹¹⁶ 17 CFR 240.15c3–5.

¹¹⁷ Current Rule 6.41–O is held as Reserved. The Exchange proposes to renumber the proposed rule with the “P” modifier and remove reference to “Reserved.”

Primary Market, plus a specified threshold to be determined by the Exchange and announced by Trader Update. This proposed rule is substantially similar to current Rule 6.60–O(c)(1)(B) for orders, with two differences. First, the proposed “Arbitrage Checks” would also apply to quotes. Second, because the Exchange is monitoring last sales from the Primary Market, the Exchange proposes that the Exchange-specified threshold for the Checks would be based on the last sale on the Primary Market rather than on the Consolidated Last Sale.¹¹⁸ The Exchange believes that the last sale on the Primary Market would be indicative of the price of the underlying security and that by using the last sale of the Primary Market rather than the Consolidated Last Sale, the Pillar system would need to ingest and process less data, thereby improving efficiency and performance of the system. The Exchange believes this proposed difference would not compromise the price protection feature of the proposed Arbitrage Checks.

Proposed Rule 6.41P–O(c) would set forth the “Intrinsic Value Checks” for orders or quotes to sell, which are designed to protect sellers of calls and puts from presumptively erroneous executions based on the “Intrinsic Value” of an option.

- Proposed Rule 6.41P–O(c)(1)(2) would set forth how the Intrinsic Value of an option would be determined. Proposed Rule 6.41P–O(c)(1) would provide that the Intrinsic Value for a put option is equal to the strike price minus the last sale price of the underlying security on the Primary Market. Proposed Rule 6.41P–O(c)(2) would provide that the Intrinsic Value for a call option is equal to the last sale price of the underlying security on the Primary Market minus the strike price. Proposed Rule 6.41P–O(c)(1)–(2) is based on how the intrinsic value is calculated in current Rule 6.60–O(c)(2) for orders, with two differences. First, the proposed “Intrinsic Value Checks” would also apply to quotes. Second, the Intrinsic Value of an option would be based on the last sale on the Primary Market rather than on the Consolidated Last Sale for the same reasons discussed above, that it would enhance performance without compromising the price protection feature of the Intrinsic Value Checks.

- Proposed Rule 6.41P–O(c)(3) would provide that ISOs to sell would not be subject to the Intrinsic Value Check,

which carve out is substantively identical to current Rule 6.60–O(c)(2).

- Proposed Rule 6.41P–O(c)(4) would describe the application of the Intrinsic Value Checks to puts and calls to sell.

- Proposed Rule 6.41P–O(c)(4)(A) would provide that orders or quotes to sell for both puts and calls would be rejected or canceled (if resting) if the price of the order or quote is equal to or lower than its Intrinsic Value, minus a specified threshold to be determined by the Exchange and announced by Trader Update.

- Proposed Rule 6.41P–O(c)(4)(B) would provide that the Exchange-determined threshold percentage (per paragraph (c)(4)(A)) would be based on the NBB, provided that, immediately following an Auction, it would be based on the Auction Price, or, if none, the lower Auction Collar price, or, if none, the NBB.¹¹⁹ This proposed threshold percentage is similar to how the Reference Price would be determined for Trading Collars, as described above pursuant to proposed Rule 6.64P–O(a)(4). As further proposed, Rule 6.41P–O(c)(4)(B) would provide that for purposes of determining the Intrinsic Value, the Exchange would not use an adjusted NBBO. The Exchange further proposes that the Intrinsic Value Check for sell orders and quotes would not be applied if the Intrinsic Value cannot be calculated.

Proposed Rule 6.41P–O(c)(4)(A)–(B) is substantially similar to current Rule 6.60–O(a)(2)(A), which describes the application of the Intrinsic Value check for orders, except that the proposed rule also applies to quotes, provides additional detail regarding how the specified threshold percentage would be determined immediately following an Auction, provides transparency that an unadjusted NBBO would be used to calculate the Intrinsic Value, and adds explicit rule text providing that if the Intrinsic Value cannot be calculated, the Check would not be applied. The Exchange believes that these additions would both add granularity to the rule and enhance the functionality by fine-tuning how the Intrinsic Value would be calculated and applied. For the same reasons describe above in connection with Limit Order Price Protection and Trading Collars, the Exchange believes that using an unadjusted NBBO would serve price protection purposes by using a more conservative view of the NBBO.

Proposed Rule 6.41P–O(d) would provide the Automated Breach Action to

be applied when a Market Maker’s order or quote fails one of the Price Reasonability Checks. As proposed, if a Market Maker’s order or quote message is rejected or cancelled (if resting) pursuant to proposed paragraph (b) (Arbitrage Checks) or (c) (Intrinsic Value Checks) of proposed Rule 6.41P–O, the Exchange would Cancel and Block orders and quotes in the affected class of options as described in Rule 6.40P–O(c)(2)(C)(iii) (as described above in section “Proposed Rule 6.40P–O”).

Proposed Rule 6.41P–O(d)(1) would provide that a breach of proposed Rule 6.41P–O(d) would count towards a Market Maker’s Global Risk Control limit per Rule 6.40P–O(a)(4) (as described above in section “Proposed Rule 6.40P–O”).

Proposed Rule 6.41P–O(d)(2) concerns how a Market Maker would be reinstated following an automated breach action. As proposed, the Exchange would not reinstate the Market Maker’s ability to enter orders and quotes and related instructions on the Exchange in that class of options (other than instructions to cancel one or more orders/quotes (including Auction-Only Orders and orders designated GTC) in full) without the consent of the Market Maker, which may be provided via automated contact.

Rule 6.41P–O(d) is substantially similar to current Rule 6.61–O(b), except that the proposed rule applies to both the orders and quotes of a Market Maker (not just quotes) and provides the additional functionality that a breach of the Price Reasonability Checks would count towards a Market Maker’s Global Risk Control limit under proposed Rule 6.40P–O(c)(3), which functionality would be new under Pillar. The Exchange believes that the proposed new functionality would provide OTP Holders and OTP Firms greater control and flexibility over setting risk tolerance and exposure for both orders and quotes. In connection with proposed Rule 6.41P–O, the Exchange proposes to add the following preamble to Rules 6.60–O and 6.61–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rules 6.60–O and 6.61–O would not be applicable to trading on Pillar.

Proposed Rule 6.64P–O: Auction Process

Current Rule 6.64–O, OX Opening Process, sets forth the opening process currently used on the Exchange’s OX system for opening trading in a series each day and reopening trading in a series following a trading halt. Current

¹¹⁸ Per proposed Rule 1.1., the term “Primary Market” means the principal market in which the underlying security is traded.

¹¹⁹ See discussion *infra*, regarding proposed Rule 6.64P–O(a) and proposed definitions for the terms “Auction,” “Auction Price,” “Auction Collar,” “pre-open state,” and “Trading Halt Auction.”

Rule 6.64(a) defines the term “Trading Auction” as the process by which trading is initiated in a specified options class that may be employed at the opening of the Exchange each business day or to re-open trading after a trading halt, and that Trading Auctions will be conducted automatically by the OX system. Current Rules 6.64–O (b) and (c) describe the manner for the automated Trading Auctions and provide that, once the primary market for the underlying security disseminates a quote and a trade that is at or within the quote, the OX System then conducts an Auction Process (“current Auction Process”) whereby the OX System determines a single price at which a series may be opened by looking to the price at which the greatest number of contracts can trade at or between the NBBO disseminated by OPRA.¹²⁰

As described in Rule 6.64–O(b)(D), the Exchange will not conduct the current Auction Process to open a series if the bid-ask differential for that series is not within an acceptable range, *i.e.*, is not within the bid-ask differential guidelines established in Rule 6.37–O(b)(4).¹²¹ If a series does not open for trading, market and limit orders entered in advance of the current Auction Process remain in the Consolidated Book and will not be routed, even if another exchange opens that series for trading and such resting orders become Marketable against an away market NBBO.¹²²

The Exchange proposes that new Rule 6.64P–O would set forth the automated process for both opening and reopening trading in a series on the Exchange on Pillar. The Exchange proposes to specify that current Rule 6.64–O would not be applicable to trading on Pillar. With the transition to Pillar, the fundamental process of how an option series would be opened (or reopened) on the Exchange would not materially change

¹²⁰ If the same number of contracts can trade at multiple prices, the opening price is the price at which the greatest number of contracts can trade that is at or nearest to the midpoint of the NBBO disseminated by OPRA; unless one such price is equal to the price of any resting Limit Order(s) in which case the opening price is the same price as the Limit Order(s) with the greatest size and, if the same size, the highest price and if there is a tie between price levels and no Limit Orders exist at either of the prices, the Exchange uses the higher price. See Rule 6.64–O(c).

¹²¹ Because Rule 6.64–O(b)(D) cross-references the bid-ask differential requirement of Rule 6.37–O(b)(4), which relates to the obligations of Market Makers in appointed classes, the Exchange will not open a series for trading if the NBBO disseminated by OPRA in a series is not within such bid-ask differentials.

¹²² The term “Marketable” is defined in proposed Rule 1.1 to mean for a Limit Order, an order that can be immediately executed or routed and Market Orders are always considered marketable.”

because the Exchange would continue to assess whether a series can be opened based on whether the bid-ask differential for a series is within a specified range. However, with the availability of Pillar technology, the Exchange proposes differences to the proposed auction process that are designed to provide additional opportunities for an options series to open or reopen for trading even if the bid-ask differential is wider than the specified guidelines. While this proposed functionality would be new for options trading on the Exchange, it is not novel for an options exchange to provide additional opportunities for a series to open after a specified period of time in a wide market.¹²³ The Exchange believes that the proposed changes would enhance the opening/reopening process on the Exchange by providing a transparent and deterministic process for the Exchange to open additional series for trading.

Further, the Exchange proposes additional enhancements (and detail them in the rule) that are based on existing Pillar functionality for the Exchange’s cash equity platform’s electronic auctions relating to how orders and quotes would be processed if they arrive during the period when the Exchange is processing an Auction and how the Exchange would process orders and quotes when it transitions to continuous trading following an Auction. Because the Exchange would be using Pillar terminology, the Exchange proposes to structure proposed Rule 6.64P–O based in part on Rule 7.35–E, which is the Exchange’s cash equity rule governing auctions (relating to separate sections describing definitions, order processing during an Auction Processing Period, and transition to continuous trading) and NYSE Rule 7.35, which is NYSE’s rule governing auctions (relating to separate sections describing definitions, Auction Ranking, Auction Imbalance Information, order processing during an Auction Processing Period, and transition to continuous trading). In addition, the Exchange proposes to include in Rule 6.64P–O how the Exchange would process orders and

¹²³ For example, Cboe recently amended Cboe Rule 5.31 relating to its opening process to provide for a “forced opening” process that is used if an option class is unable to open because it does not meet the applicable bid-ask differential. In such case, if the “Composite Market” is not crossed and there is no non-zero offer, within a specified time period, Cboe will open the series without a trade. See Securities Exchange Act Release No. 90967 (January 22, 2021), 86 FR 7249 (January 28, 2021) (SR–Cboe–2021–005) (Notice of filing and immediate effectiveness of proposed rule change to amend Cboe’s opening process for simple orders).

quotes during a trading halt, which is structured based in part on Rule 7.18–E(b) and (c), which describe how the Exchange processes new and existing orders during a trading halt on its cash equity market. This text would be new and is designed to provide granularity and transparency in Exchange rules.

Definitions. Proposed Rule 6.64P–O(a) would provide that the Rule would be applicable to all series that trade on the Exchange other than Flex Options.¹²⁴ Proposed Rule 6.64P–O(a) would set forth the definitions that would be used for purposes of Rule 6–O Options Trading and applicable to trading on Pillar. Certain of the proposed definitions are the same as (or similar to) auction-related definitions used on the Exchange’s cash equity platform, per Rule 7.35–E (Auctions), with differences noted herein. To the extent that a definition from Rule 7.35–E is not utilized in proposed Rule 6.64P–O, the Exchange has determined that such definition(s) is either inapplicable to the opening process for options trading or that the relevant, analogous concept(s) is covered elsewhere in the proposed rule.

- Proposed Rule 6.64P–O(a)(1) would define the term “Auction” to mean the opening or reopening of a series for trading either with or without a trade. This proposed definition is based in part on current Rule 6.64–O(a), which defines the term “Trading Auction” to be a process by which trading is initiated in a specified options class that may be employed at the opening of the Exchange each business day or to re-open trading after a trading halt.¹²⁵ On Pillar, the Exchange proposes that the term “Auction” would refer to the point in the process where the Exchange determines that a series can be opened or reopened either with or without a trade. After an Auction concludes, the series then transitions to continuous trading. Proposed Rule 6.64P–O(a)(1)(A) would provide that a “Core Open Auction” means the Auction that opens trading after the beginning of Core Trading Hours and proposed Rule 6.64P–O(a)(1)(B) would provide that a

¹²⁴ With the transition to Pillar, the Exchange is not making any changes to how Flex Options trade. Rule 5.31–O provides that Flex Options transactions may be effected during normal Exchange options trading hours on any business day and there will be no trading rotations in Flex Options. Rule 5.33–O sets forth the procedures for trading Flex Options. The opening process for Electronic Complex Orders is set forth in Rule 6.91–O.

¹²⁵ See also Rule 6.64–O(d) (providing that a Trading Auction to reopen an option class after a trading halt is conducted in the same manner as a Trading Auction to open each option class at the start of each trading day, *i.e.*, as described in Rule 6.64–O(a)–(c)).

“Trading Halt Auction” means the Auction that reopens trading following a trading halt. These are Pillar terms that would be new to options trading and are based on the same terms currently used in Rule 7.35–E(c) and (e) for the same purposes.

- Proposed Rule 6.64P–O(a)(2) would define the term “Auction Collar” to mean the price collar thresholds for the Indicative Match Price (defined below) for an Auction. As further proposed, the upper Auction Collar would be the offer of the Legal Width Quote (defined below) and the lower Auction Collar would be the bid of the Legal Width Quote, provided that if the bid of the Legal Width Quote is zero, the lower Auction Collar would be one MPV above zero for the series. The proposed rule would further provide that if there is no Legal Width Quote, the Auction Collars would be published in the Auction Imbalance Information (defined below) as zero.

The proposed terminology of “Auction Collar” would be new for options trading and is based on the same term used in Rule 7.35–E(a)(10) for trading cash equity securities. As proposed, the Auction Collars would be set at the Legal Width Quote (described below) and would prevent an Auction trade from occurring at a price outside of the Legal Width Quote. The Exchange believes that the concept of Auction Collars is similar to the current requirement that the Exchange will not open a series if the bid-ask differential is not within the bid-ask differential guidelines established under Rule 6.37–O(b)(4).¹²⁶ Thus, the proposed Auction Collars (based on a Legal Width Quote) would use Pillar terminology to prevent an Auction that results in a trade from being priced outside the bid-ask differential applicable to Auctions on Pillar.¹²⁷

- Proposed Rule 6.64P–O(a)(3) would define the term “Auction Imbalance Information” to mean the information that the Exchange disseminates about an Auction via its proprietary data feeds and includes the Auction Collars, Auction Indicator, Book Clearing Price, Far Clearing Price, Indicative Match Price, Matched Volume, Market Imbalance, and Total Imbalance.¹²⁸

With Pillar, the Exchange proposes to disseminate Auction Imbalance Information for its options market in the same manner that such information is disseminated for its cash equity market. The Exchange currently makes certain auction imbalance information available on its proprietary data feed and the Exchange believes that enhancing this information by disseminating the proposed Auction Collars, Auction Indicator, Book Clearing Price, and Far Clearing Price, which would be new for options trading on Pillar, would promote transparency. Accordingly, this proposed definition would be new and is based on the same term used in Rule 7.35–E(a)(4), with differences to reflect the options-specific content that would be included in Auction Imbalance Information for options trading. In addition, the Exchange proposes that the Auction Imbalance Information would reflect the orders and quotes eligible to participate in an Auction, which contribute to price discovery. Accordingly, proposed Rule 6.64P–O(a)(3) would further provide that Auction Imbalance Information would be based on all orders and quotes (including the non-displayed quantity of Reserve Orders) eligible to participate in an Auction, excluding IO Orders.¹²⁹ The Exchange believes that specifying that non-displayed quantity of Reserve Orders would be included in the Auction Imbalance Information is consistent with current functionality that the full quantity of Reserve Orders are eligible to participate in the current Auction Process.

Proposed Rule 6.64P–O(a)(3)(A) would define the term “Auction Indicator” to mean the indicator that provides a status update of whether an Auction cannot be conducted because either (i) there is no Legal Width Quote, or (ii) a Market Maker quote has not been received during the Opening MMQ Time Parameter (defined below). The Exchange currently disseminates an Auction Indicator on its cash equity market and proposes similar functionality for options trading on the Exchange.¹³⁰ This proposed definition would be new for options trading and uses Pillar terminology based on Rule

trading and does not propose to include such a period for options trading on Pillar. Accordingly, the Exchange does not propose terms based on “Auction Imbalance Freeze,” as described in Rule 7.35–E(a)(3), for options trading on Pillar.

¹²⁹ This is consistent with the order information included in Auction Imbalance Information for cash equity trading. See Rule 7.35–E(a)(7) and 7.35–E(a)(8). The Exchange proposes to exclude IO Orders because they are conditional offsetting orders that would not contribute to price discovery in the Auction Process.

¹³⁰ See Rule 7.35–E(a)(13).

7.35–E(a)(13) and would provide transparency of when an Auction could not be conducted.¹³¹ While the Exchange’s cash equity rule is written from the standpoint of when an auction *can* be conducted, the proposed rule is written from the standpoint of when an auction *cannot* be conducted. The Exchange believes this difference is appropriate because, for options trading, the proposed Auction (and its Auction Indicator) are impacted by the absence of necessary information (*i.e.*, a Legal Width Quote or a Market Maker quote), rather than an auction in the cash equity market, where the determining factor of whether to conduct an auction is the quality (not the presence of) of information (*i.e.*, the Imbalance).

Proposed Rule 6.64P–O(a)(3)(B) would define the term “Book Clearing Price” to mean the price at which all contracts could be traded in an Auction if not subject to the Auction Collar and states that the Book Clearing Price would be zero if a sell (buy) Imbalance cannot be filled by any buy (sell) interest. The Exchange proposes that the manner that the Book Clearing Price would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition and functionality would be new for options trading and is based on the definition of “Book Clearing Price” set forth in Rule 7.35–E(a)(11), with differences to reflect options trading terminology (*i.e.*, reference contracts instead of buy (sell) orders).

Proposed Rule 6.64P–O(a)(3)(C) would define the term “Far Clearing Price” to mean the price at which Auction-Only Orders could be traded in an Auction within the Auction Collar. The Exchange proposes that the manner that the Far Clearing Price would be calculated for options trading would be the same as how it is calculated for cash equity trading. Accordingly, this proposed definition and functionality would be new for options trading and is based on the definition of “Far Clearing Price” set forth in Rule 7.35–E(a)(12).

Proposed Rule 6.64P–O(a)(3)(D) would define the term “Imbalance” to mean the number of buy (sell) contracts that cannot be matched with sell (buy) contracts at the Indicative Match Price at any given time. The Exchange proposes that the manner that the Imbalance would be calculated for options trading would be the same as how it is calculated for cash equity

¹³¹ Consistent with the proposed rule, Rule 6.64–O(b)(D) provides that the Exchange will not conduct the current Auction Process if the bid-ask differential for a series is not within an acceptable range.

¹²⁶ See Rule 6.64–O(b)(D) and (E). The Exchange notes that in common parlance bid-ask differentials are known as “legal-width quotes.”

¹²⁷ See also Cboe Rule 5.31(a) (defining the “Opening Collar” as the price range that establishes limits at or inside of which Cboe determines the opening trade price for a series).

¹²⁸ On the Exchange’s cash equity market, Auctions have an “Auction Imbalance Freeze,” which is a period in advance of the scheduled Auction. The Exchange does not currently provide for an analogous period to open or reopen options

trading, which is consistent with current functionality that calculates the imbalance based on all interest eligible to participate in an auction. Accordingly, this proposed definition would be new rule text for options trading and is based on the definition of “Imbalance” set forth in Rule 7.35–E(a)(7), except that, unlike for cash equities, the proposed definition would not reference the non-displayed quantity of Reserve Orders. As discussed above, the Exchange believes that providing an overarching description of how the non-displayed quantity of Reserve Orders would be included in Auction Imbalance Information is more appropriately included in the proposed (more expansive) definition of Auction Imbalance Information (per proposed Rule 6.64P–O(a)(3)) to reflect the Auction-eligible interest that contribute to price discovery.¹³² In addition, the proposed rule differs from Rule 7.35–E(a)(7) to reflect options trading terminology (*i.e.*, contracts instead of shares).

Proposed Rule 6.64P–O(a)(3)(D)(i) would define the term “Total Imbalance” to mean the Imbalance of all buy (sell) contracts at the Indicative Match Price for all orders and quotes eligible to trade in an Auction. The Exchange proposes that the manner that the Total Imbalance would be calculated for options trading would be the same as how it is calculated for cash equity trading and is consistent with current functionality. Accordingly, this proposed definition would be new and is based on the definition of “Total Imbalance” set forth in Rule 7.35–E(a)(7)(A), except that the proposed definition does not include the superfluous modifier “net” in reference to Total Imbalance and includes options trading terminology (*i.e.*, contracts instead of shares).

Proposed Rule 6.64P–O(a)(3)(D)(ii) would define the term “Market Imbalance” to mean the Imbalance of any remaining buy (sell) Market Orders and MOO Orders that are not matched for trading in the Auction. The Exchange proposes that the manner that the Market Imbalance would be calculated for options trading would be the same as how it is calculated for cash equity trading, which differs from current options functionality.¹³³ Accordingly, this proposed definition

and functionality would be new and is based on the definition of “Market Imbalance” set forth in Rule 7.35–E(a)(7)(B), with a difference to add reference to MOO Orders (as defined in proposed Rule 6.62P–O(c)(2)).¹³⁴

• Proposed Rule 6.64P–O(a)(4) would define the term “Auction Price” to mean the price at which an Auction that results in a trade is conducted. The Exchange proposes that this term would have the same meaning as the same term on its cash equity market, per Rule 7.35–E(a)(2), with a difference to add the phrase “that results in a trade” to be clear that an Auction Price is for an Auction that results in a trade. This would be a new term and is designed to add clarity and transparency to Exchange rules as this term would be used as a reference price in proposed Rules 6.62P–O(a)(3)(B) and 6.41P–O(c)(4)(B).¹³⁵

• Proposed Rule 6.64P–O(a)(5) would define the term “Auction Process” to mean the process that begins when the Exchange receives an Auction Trigger (defined below) for a series and ends when the Auction is conducted. This would be a new term and is designed to add clarity and transparency to Exchange rules and address all steps in the process that culminates in an Auction, as described in proposed Rule 6.64P–O(d).

• Proposed Rule 6.64P–O(a)(6) would define the term “Auction Processing Period” to mean the period during which the Auction is being processed. The Exchange proposes that this new term would have the same meaning as the same term on its cash equity market. The Auction Processing Period is at the end of the Auction Process and is the period when the actual Auction is conducted and the Exchange transitions from a pre-open state (described below) to continuous trading. The end of the Auction Processing Period is the end of the Auction and, depending on the orders and quotes in the Consolidated Book, it concludes either with or without a trade. Accordingly, this proposed definition is substantively

¹³⁴ Rule 7.35–E(a)(7)(B) does not separately reference MOO Orders because Rule 7.35–E(a) provides that, unless otherwise specified, the term “Market Orders” in Rule 7.35–E includes MOO Orders (for the Core Open Auction and Trading Halt Auction). The Exchange proposes that for options trading, the terms Market Order and MOO Order both be referenced in proposed Rule 6.64P–O.

¹³⁵ See also Cboe Rule 5.31(a) (defining the “Opening Trade Price” as the price at which Cboe executes opening trades in a series). The Exchange notes that the term “Auction Price” is distinguished from the proposed term of “Indicative Match Price,” as the latter term is the content included in the Auction Imbalance Information in advance of an Auction, and the Auction Price is the price of an Auction that results in a trade.

identical to the definition of “Auction Processing Period” set forth in Rule 7.35–E(a)(2).

• Proposed Rule 6.64P–O(a)(7) would define the term “Auction Trigger” to mean the information disseminated by the Primary Market in the underlying security that triggers the Auction Process for a series to begin. For a Core Open Auction, the proposed Auction Trigger would be when the Primary Market first disseminates at or after 9:30 a.m. Eastern Time both a two-sided quote and a trade of any size that is at or within the quote. For a Trading Halt Auction, the proposed Auction Trigger would be when the Primary Market disseminates at the end of a trading halt or pause a resume message, a two-sided quote, and a trade of any size that is at or within the quote. This proposed term is new and is not used on the cash equity platform. This proposed functionality, however, is not new and is based on how the Exchange currently opens or reopens a series for trading, as set forth in the last sentence of current Rule 6.64–O(b).¹³⁶ The proposed rule adds detail not found in the current rule by referring to a “two-sided quote” rather than a “quote,” without any changes to functionality. The Exchange also proposes a difference that an opening trade on the Primary Market may be “of any size,” which would make clear that an odd-lot transaction on the Primary Market could be used as an Auction Trigger, which would be new on Pillar.¹³⁷ The Exchange believes that because it requires both a quote and a trade from the Primary Market before it can open/reopen trading in the overlying option, and because a Primary Market that has disseminated a quote for an underlying security is open for trading, allowing odd-lot sized trades to be included in the trigger would increase the opportunities to open/reopen trading options that overlay low-volume securities that have opened for trading on the Primary Market and would reduce the circumstances needed to manually trigger an Auction for a series.

• Proposed Rule 6.64P–O(a)(8) would define the term “Calculated NBBO” to mean the highest bid and lowest offer

¹³⁶ Rule 6.64–O(b) provides, in relevant part, that the related option series will be opened automatically “once the primary market for the underlying security disseminates a quote and a trade that is at or within the quote.”

¹³⁷ See also Cboe Rule 5.31(d)(1)(ii), which provides that Cboe initiates the opening rotation for equity options after “both the first disseminated transaction and the first disseminated quote on the primary market in the security underlying an equity option,” which rule does not specify the size of the transaction on the primary market that would trigger initiation of an opening rotation.

¹³² See *supra* note 129 (regarding consistency of proposed Rule 6.64P–O(a)(3) regarding Auction Imbalance Information with Rule 7.35–E(a)(7) and 7.35–E(a)(8)).

¹³³ On the OX system, the market imbalance is the difference between quantities of buy and sell market orders.

among all Market Maker quotes and the Away Market NBBO during the Auction Process. The Exchange proposes to use the term “Calculated NBBO” to specify which bids and offers the Exchange would consider for purposes of determining whether to proceed with an Auction on Pillar, as described in greater detail below. The Exchange believes the proposed term provides more clarity than referencing an “NBBO disseminated by OPRA.”¹³⁸

- Proposed Rule 6.64P–O(a)(9) would define the term “Indicative Match Price” to mean the price at which the maximum number of contracts can be traded in an Auction, including the non-displayed quantity of Reserve Orders, and excluding IO Orders, subject to the Auction Collars. This functionality is consistent with the current process for establishing a single opening price, as described in Rule 6.64–O(b)(A), but the proposed rule adds more granularity and uses Pillar terminology.¹³⁹ In addition, the term “Indicative Match Price” refers to the same functionality as the OX system’s reference to the term “reference price” in its imbalance information. This proposed definition is based on the Pillar definition of “Indicative Match Price” set forth in Rule 7.35–E(a)(8), with differences to refer solely to “price” as opposed to “best price” because proposed Rule 6.64P–O(a)(9)(A), described below, would provide specificity of how such price would be determined, and to reflect options trading terminology (*i.e.*, contracts instead of shares). Proposed Rule 6.64P–O(a)(9) would further provide that if there is no Legal Width Quote, the Indicative Match Price included in the Auction Imbalance Information would be calculated without Auction Collars. This would be a new feature applicable only to options trading and an Indicative Match Price without Auction Collars would be accompanied with an Auction Indicator that the Auction cannot be conducted because there is no Legal Width Quote.¹⁴⁰

¹³⁸ The Exchange notes that the information used to calculate the proposed Calculated NBBO is consistent with the information that the Exchange receives from OPRA in advance of the Exchange opening or reopening trading (*i.e.*, Market Maker rotational quotes from the Exchange and Away Market NBBO) and is similar to Cboe’s definition of “Composite Market,” as described in Cboe Rule 5.31(a), which includes Cboe Market Maker quotes and BBOs of other options exchanges.

¹³⁹ See Rule 6.64–O(b)(A), (c) (describing process for determining single opening price).

¹⁴⁰ This would be new functionality because currently, if there is no legal width NBBO, the Exchange does not disseminate imbalance information and does not calculate an indicative match price.

Proposed Rule 6.64P–O(a)(9)(A) would provide that if there is more than one price level at which the maximum number of contracts can be traded within the Auction Collars, the Indicative Match Price would be the price closest to the midpoint of the Legal Width Quote, rounded to the nearest MPV for the series, provided that the Indicative Match Price would not be lower (higher) than the highest (lowest) price of a Limit Order to buy (sell) ranked Priority 2—Display Orders that is eligible to participate in the Auction. This functionality is similar to the current process for establishing a single opening price, as described in Rule 6.64–O(c), which provides that when the same number of contracts can trade at multiple prices, the opening price is the price at which the greatest number of contracts can trade that is at or nearest to the midpoint of the NBBO disseminated by OPRA. The proposed rule text uses Pillar terminology based on Rule 7.35–E(a)(8)(A) and adds more granularity, such as describing that the Exchange would round to the nearest MPV in the series, which is consistent with current functionality. The Exchange also proposes a difference compared to the cash equity rules to reflect that when there is more than one price level at which the maximum number of contracts can trade, the Indicative Match Price for options trading would be the price closest to the midpoint of the Legal Width Quote rather than (for cash equities) the price closest to an auction reference price. The Exchange believes that reference to the term Legal Width Quote reflects the proposed use of this term in the Auction Process rather than referring to the NBBO disseminated by OPRA.

Proposed Rule 6.64P–O(a)(9)(B) would provide that an Indicative Match Price that is higher (lower) than the upper (lower) Auction Collar would be adjusted to the upper (lower) Auction Collar and orders eligible to participate in the Auction would trade at the collared Indicative Match Price. Proposed Rule 6.64P–O(a)(9)(B)(i) would provide that Limit Orders to buy (sell) with a limit price above (below) the upper (lower) Auction Collar would be included in the Auction Imbalance Information at the collared Indicative Match Price and would be eligible to trade at the Indicative Match Price. This proposed rule text provides granularity that, consistent with current functionality, orders willing to buy (sell) at a higher (lower) price than the Auction Price would participate in an Auction trade, which, by definition, would be required to be at or between

the Auction Collars. Proposed Rule 6.64P–O(a)(9)(B)(ii) would provide that Limit Orders and quotes to buy (sell) with a limit price below (above) the lower (upper) Auction Collar would not be included in the Auction Imbalance Information and would not participate in an Auction. The Exchange proposes that the manner that orders and quotes priced outside of the Auction Collar would be included (or not) in the Indicative Match Price would be the same as how it is determined for cash equity trading. Accordingly, this proposed rule text is new for options trading (but the functionality is consistent with current functionality) and uses Pillar terminology based on Rules 7.35–E(a)(10)(A), (B), and (C) that is designed to add granularity to the proposed rule, and with a difference to reflect when the proposed rule would be applicable to quotes.

Proposed Rule 6.64P–O(a)(9)(C) would provide that if the Matched Volume (defined below) for an Auction consists of only buy and sell Market Orders, the Indicative Match Price would be the midpoint of the Legal Width Quote, rounded to the MPV for the series, or, if, the Legal Width Quote is locked, then the locked price. This proposed rule text is new and uses Pillar terminology based on Rule 7.35–E(a)(8)(C), with differences to reflect that options trading on Pillar would be based on a Legal Width Quote (as defined herein) to determine the Indicative Match Price when there are only Market Orders eligible to trade in an Auction. This proposed rule is designed to provide granularity of how the Indicative Match Price would be calculated if there are only Market Orders.

Proposed Rule 6.64P–O(a)(9)(D) would provide that if there is no Matched Volume, including if there are Market Orders on only one side of the Market, the Indicative Match Price and Total Imbalance for the Auction Imbalance Information would be zero. This proposed rule text is new and uses Pillar terminology based on Rule 7.35–E(a)(8)(D) and (E) with differences to reflect that on options, the Indicative Match Price would be zero in both circumstances. This proposed Rule is designed to provide granularity regarding how the Indicative Match Price and Total Imbalance for the Auction Imbalance Information would be calculated if there is no Matched Volume.

- Proposed Rule 6.64P(a)(10) would define a “Legal Width Quote” as a Calculated NBBO that: (A) May be locked, but not crossed; (B) does not contain a zero offer; and (C) has a spread

between the Calculated NBBO for each option contract that does not exceed the following differentials, which can be widened as provided for in Rule 6.37–O(c): (i) No more than .25 where the bid does not exceed \$2; (ii) no more than .40 where the bid is more than \$2 but does not exceed \$5; (iii) no more than .50 where the bid is more than \$5 but does not exceed \$10; (iv) no more than .80 where the bid is more than \$10 but does not exceed \$20; and (v) no more than \$1 where the bid is more than \$20, provided that a Trading Official may establish differences other than the above for one or more series or classes of options.¹⁴¹

Requiring that the Legal Width Quote not be crossed is consistent with current Rule 6.64–O(b)(E), which requires an uncrossed NBBO disseminated by OPRA before a series can be opened (or reopened).¹⁴² The Exchange believes that the additional detail in proposed Rules 6.64P–O(a)(10)(A) and (B) regarding how to determine a Legal Width Quote provides clarity and granularity the circumstances when a Calculated NBBO would be eligible to be considered a Legal Width Quote.

In addition, requiring that a bid-ask spread meet specified differentials, described in proposed Rule 6.64P–O(a)(10)(C)(i)–(v), before an Auction can proceed is based on the current OX Opening Process, which requires the bid-ask differential for a series to be in an acceptable range.¹⁴³ The proposed differential spread for the Pillar Auction Process set forth in proposed Rule 6.64P–O(a)(10)(C) are substantially the same as the bid-ask differentials (as well as the discretion granted a Trading Official to widen such differentials) currently set forth in Rule 6.37–O(b)(4), with a difference that for option contracts with a bid of exactly \$2, the differential for Auctions on Pillar would be .25 instead of .40. The Exchange notes that this slight variation from Rule

6.37–O(b)(4)(A) for \$2 bids would streamline implementation by having the break point for bid-differentials for the automated Auction Process to be calculated in whole dollar increments. The Exchange believes that including the proposed bid-ask differential in the rule governing the Auction Process would promote clarity and transparency in Exchange rules regarding which quotes—both Market Maker quotes on the Exchange and the Away Market NBBO, *i.e.*, the Calculated NBBO—that the Exchange would use to determine if there is a Legal Width Quote.

The Exchange also proposes to make a conforming change to Rule 6.37–O(c) to update the title from “Unusual Conditions—Opening Auction” to be “Unusual Conditions—Auctions,” which would align with the proposed definition of “Auctions” in proposed Rule 6.64P–O(a), which includes both opening and reopening auctions. This proposed change also promotes clarity, consistent with current functionality that Rule 6.37–O(c) is also applicable to reopenings. In addition, the Exchange proposes to amend Rule 6.37–O(c), which authorizes a Trading Official to widen the bid-ask differentials in the event of unusual conditions, to add a cross-reference to extend such authority to proposed Rule 6.64P–O(a)(9) (regarding the Legal Width Quote spreads). This proposed amendment would ensure that the existing procedures for auctions in the event of unusual conditions, as specified in Rule 6.37–O(c), would continue to be available for option symbols that have transitioned to Pillar (and subject to new Rule 6.64P–O(a)(10)).

- Proposed Rule 6.64P–O(a)(11) would define the term “Matched Volume” to mean the number of buy and sell contracts that can be matched at the Indicative Match Price, excluding IO Orders. The concept of Matched Volume on Pillar is consistent with the OX system’s concept of “paired quantity” in its imbalance information. This proposed rule text uses Pillar terminology based on the definition of “Matched Volume” set forth in Rule 7.35–E(a)(9), with a non-substantive difference to reference (option) contracts instead of shares and to be clear that the Matched Volume would not include IO Orders. The Exchange believes this proposed definition promotes granularity in Exchange rules.

- Proposed Rule 6.64P–O(a)(12) would define the term “pre-open state” to mean the period before a series is opened or reopened for trading and would provide that during the pre-open state, the Exchange would accept Auction-Only Orders, quotes, and

orders designated Day or GTC, including orders ranked under the proposed category of “Priority 3—Non-Display Orders” that are not eligible to participate in an Auction.¹⁴⁴ This proposed text is consistent with current Rule 6.64–O(b), which provides that the Exchange will accept market and limit orders for inclusion in the opening auction process and would add further granularity regarding which interest would be accepted by the Exchange (even if not eligible for an Auction) prior to the opening or reopening of each option series and during which time period. The proposed rule would further provide that the pre-open state for the Core Open Auction would begin at 6:00 a.m. Eastern Time and would end when the Auction Processing Period begins, which is similar to current functionality, which allows order and quote entry to begin at 5:30 a.m. Eastern Time. The Exchange believes that moving the start time to 6:00 a.m. Eastern Time would not materially impact the ability of OTP Holders to enter orders or quotes during the pre-open state. As further proposed, at the beginning of the pre-open state before the Core Open Auction, orders designated GTC that remain from the prior trading day will be included in the Consolidated Book, which is consistent with current functionality. The proposed rule would also provide that the pre-open state for a Trading Halt Auction would begin at the beginning of the trading halt and would end when the Auction Processing Period begins. This proposed definition of a pre-open state would be new for Pillar and is designed to distinguish the pre-open state (for a Core Open Auction or a Trading Halt Auction) from both the Auction Processing Period and the period when a given series opens for trading, which would add granularity to Exchange rules. As noted above, this proposed definition of pre-open state would also be used in proposed Rules 6.40P–O, 6.41P–O, and 6.62P–O.

- Proposed Rule 6.64P–O(a)(13) would define the term “Rotational Quote” to mean the highest Market Maker bid and lowest Market Maker offer on the Exchange when the Auction Process begins and would provide that during the Auction Process, the

¹⁴¹ See Rule 6.37–O(c) (Unusual Conditions—Opening Auction) (providing that “[i]f the interest of maintaining a fair and orderly market so requires, a Trading Official may declare that unusual market conditions exist in a particular issue and allow Market Makers in that issue to make auction bids and offers with spread differentials of up to two times, or in exceptional circumstances, up to three times, the legal limits permitted under Rule 6.37–O”).

¹⁴² The proposed calculation of a Legal Width Quote is also similar to how Cboe determines whether to perform a “Forced Opening,” because Cboe requires a Composite Market that is not crossed with a non-zero offer. See Cboe Rule 5.31(e)(4).

¹⁴³ See Rule 6.64–O(b)(D) (providing that “[t]he OX System will not conduct an Auction Process if the bid-ask differential for that series is not within an acceptable range,” which “acceptable range shall mean within the bid-ask differential guidelines established pursuant to Rule 6.37–O(b)(4)”).

¹⁴⁴ The Exchange notes that Cboe refers to a similar period as the “Queuing Period.” See Cboe Rule 5.31(b). Similar to Cboe’s Queuing Period, the proposed term of “pre-open state” means the period when the Exchange accepts orders and quotes but has not yet opened/reopened a series for continuous trading. The proposed “Auction Process,” defined above, is part of the pre-open state, but does not begin until the Exchange receives an Auction Trigger, as defined above.

Exchange would update the price and size of the Rotational Quote and that such Rotational Quote can be locked or crossed. The Exchange further proposes that, if there are no Market Maker quotes, the Rotational Quote would be published with a zero price and size. The Exchange notes that, although not specified in the current rule, it currently disseminates a “rotational quote” to OPRA when it is in the process of opening or reopening a series, *i.e.*, a quote that is comprised only of Market Maker quotes and does not include orders. The Exchange proposes a difference on Pillar because currently, if the Market Maker Quotes are crossed, the Exchange flips the bid and offer prices. In Pillar, the Exchange would publish a Rotational Quote with the actual bid and offer prices, even if crossed, which would provide OTP Firms and OTP Holders with a more accurate view of whether a Rotational Quote is crossed. This proposed definition is new, uses Pillar terminology, and adds granularity to Exchange rules by codifying existing (albeit slightly modified) functionality.

Auction Ranking. Proposed Rule 6.64P–O(b) would describe the ranking for Auctions and would provide that orders and quotes on the side of the Imbalance are not guaranteed to participate in the Auction and would be ranked in price-time priority under proposed Rule 6.76P–O, consistent with the priority ranking associated with each order or quote, provided that: (1) Limit Orders, quotes, and LOO Orders would be ranked based on their limit price and not the price at which they would participate in the Auction; (2) MOO Orders would be ranked under the proposed category of “Priority 1—Market Orders”; (3) LOO Orders would be ranked under the proposed category of “Priority 2—Display Orders”; and (4) IO Orders would be ranked based on time among IO Orders, subject to eligibility to participate at the Indicative Match Price based on their limit price.¹⁴⁵

This proposed rule is based in part on current Rule 6.64–O(b)(B), which provides that “[o]rders and quotes in the system will be matched up with one another based on price-time priority, provided, however, that orders will have priority over Market Maker quotes at the same price.” The Exchange proposes a difference in Pillar that orders in the same priority category as

quotes would not have priority over Market Maker quotes at the same price. Instead, orders and Market Maker quotes in the same priority category would be ranked based on time, as proposed in Rule 6.76P–O, which equal ranking is consistent with how other options markets handle orders and quotes during the opening process.¹⁴⁶ Because the Exchange proposes that orders and quotes in an options Auction would be processed in the same manner as on its cash equity platform, including that orders on the side of the Imbalance would not be guaranteed to participate in an Auction, the proposed rule text in this regard is based in part on Rule 7.35–E(a)(6)(A)–(D), with differences to reflect that options trading includes quotes and to be clear that IO Orders would be ranked based on working time among IO Orders, subject to such orders’ eligibility to participate at the Indicative Match Price based on their limit price.¹⁴⁷

Auction Imbalance Information. Proposed Rule 6.64P–O(c) would provide that Auction Imbalance Information would be updated at least every second until the Auction is conducted, unless there is no change to the information and would further provide that the Exchange would begin disseminating Auction Imbalance Information at the following times: (1) Core Open Auction Imbalance Information would begin at 8:00 a.m. Eastern Time; and (2) Trading Halt Auction Imbalance Information would begin at the beginning of the trading halt. Because the Exchange proposes to disseminate Auction Imbalance Information for its options market in the same manner that such information is disseminated for its cash equity market, this proposed rule text, which is new, is based in part on Rule 7.35–E(a)(4)(A) and (C).

Auction Process. Proposed Rule 6.64P–O(d) would set forth the Exchange’s proposed Auction Process on Pillar. Similar to current OX system functionality, which requires that the bid-ask differential for a given series be within an acceptable range before conducting an auction, under Pillar, a series would not be opened or reopened on a trade if there is no Legal Width

Quote, which concept, as described above, incorporates (almost identical) bid-ask differentials.¹⁴⁸ As described further below, the Exchange proposes that for Pillar, a series should (ideally) also have Market Maker quotes and, as such, proposes to provide time for Market Makers assigned to a series to quote within the specified bid-ask differentials, and if Market Makers do not quote within those time frames, determine whether to open or reopen a series based on the Away Market NBBO. The Exchange notes that this proposed process is consistent with that used on other options exchanges.¹⁴⁹

Proposed Rule 6.64P–O(d)(1) describes the process for disseminating the Rotational Quote and would provide that when the Exchange receives the Auction Trigger for a series, the Exchange would send a Rotational Quote to both OPRA and proprietary data feeds indicating that the Exchange is in the process of transitioning from a pre-open state to continuous trading for that series. This proposed rule is consistent with current functionality and is designed to promote granularity.

Proposed Rule 6.64P–O(d)(2) would provide that once a Rotational Quote has been sent, the Exchange would conduct an Auction provided there is both a Legal Width Quote and, if applicable, a Market Maker quote with a non-zero offer in the series (which would be subject to the proposed requirements relating to Market Maker quotes, including the proposed new Opening MMQ Time Parameter, as discussed further below per proposed Rule 6.64P–O(d)(3)). The proposed rule would further provide that the Exchange would wait a minimum of two milliseconds after disseminating the Rotational Quote before an Auction could be conducted, which delay would be new and is designed to enhance market quality by promoting price-forming displayed liquidity to the benefit of all market participants. This proposed rule text is designed to provide transparency and determinism

¹⁴⁸ See *supra* note 143 (describing Rule 6.64–O(b)(D), which provides that the Exchange will not conduct its current Auction Process if the bid-ask differential for a series is not “within an acceptable range”).

¹⁴⁹ See, *e.g.*, Nasdaq PHLX (“PHLX”) Section 8(d), Options Opening Process (providing that the Opening Process begins when (a) a “valid width” (*i.e.*, a bid/ask differential that is compliant with PHLX Rule 1014(c)(i)(A)(1)(a)) specialist quote is submitted, (b) valid width quotes from at least two PHLX market participants have been submitted within 30 seconds of the opening trade or quote in the underlying security from the primary exchange, or (c) after 30 seconds of the opening trade or quote in the underlying security from the primary exchange, one PHLX market participant has submitted a valid width quote).

¹⁴⁵ Unlike the Exchange’s cash equity rules, the Exchange proposes to describe Auction Ranking in a separate section of proposed Rule 6.64P–O, which is a stylistic choice similar to NYSE Rule 7.35(b), which also separates the concept of Auction Ranking from definitions.

¹⁴⁶ See Cboe Rule 5.31(e)(3)(i) (providing that Cboe “prioritizes orders and quotes in the following order: market orders, limit orders and quotes with prices better than the Opening Trade Price, and orders and quotes at the Opening Trade Price”).

¹⁴⁷ See discussion *supra*, regarding proposed Rule 6.62P–O(c)(3) and how IO Orders would function. The Exchange notes that, unlike on the cash equity platform, IO Orders would not be limited to participating solely in Trading Halt Auctions and may likewise participate in Core Open Auctions as well.

in Exchange rules regarding the earliest potential time that a series could be opened (after the Exchange receives an Auction Trigger), and subject to the series meeting all other requirements for opening or reopening discussed herein.

Subject to the requirements specified in proposed Rule 6.64P–O(d)(2), proposed Rule 6.64P–O(d)(2)(A) would provide that if there is Matched Volume that can trade at or within the Auction Collars, the Auction would result in a trade at the Indicative Match Price. Proposed Rule 6.64P–O(d)(2)(B) would provide that if there is no Matched Volume that can trade at or within the Auction Collars, the Auction would not result in a trade and the Exchange would transition to continuous trading as described in proposed Rule 6.64P–O(f) below. This proposed rule text is new, uses Pillar terminology, and is designed to provide transparency of when an Auction would result in a trade.

Proposed Rule 6.64P–O(d)(3) would specify the Opening MMQ Time Parameter. Although the Exchange does not require a Market Maker assigned to a series to quote on the Exchange in order to open or reopen a series for trading, the Exchange believes that having a Market Maker assigned to a series quote within the bid-ask differential would promote a fair and orderly Auction process and transition to continuous trading.¹⁵⁰ Accordingly, the Exchange proposes a new process for Auctions on Pillar that would provide time for Market Makers assigned to a series to quote within the specified bid-ask differentials before a series would be opened or reopened for trading. As proposed, once the Auction Process begins, the Exchange would begin a one-minute timer for the Market Maker(s) assigned to a series to submit a quote with a non-zero offer.¹⁵¹ This one-minute timer would be referred to as the Opening MMQ Time Parameter. The Opening MMQ Time Parameter is designed to provide transparency in Exchange rules of the circumstances of when the Exchange would wait to open or reopen a series for trading if the assigned Market Maker(s) has not

submitted a quote within the specified time periods, as follows:

- Proposed Rule 6.64P–O(d)(3)(A) would provide that if there are no Market Makers assigned to a series, the Exchange would conduct an Auction in that series based solely on a Legal Width Quote, without waiting for the Opening MMQ Time Parameter to end. As set forth in proposed Rule 6.64P–O(d)(2)(A) and (B), if there is Matched Volume, this Auction would result in a trade, otherwise, the series would transition to continuous trading as described in proposed Rule 6.64P–O(f) below.

- Proposed Rule 6.64P–O(d)(3)(B) would provide that if there is only one Market Maker assigned to a series:

- The Exchange would conduct the Auction, without waiting for the Opening MMQ Time Parameter to end, as soon as there is both a Legal Width Quote and the assigned Market Maker has submitted a quote with a non-zero offer (proposed Rule 6.64P–O(d)(3)(B)(i)). As set forth in proposed Rule 6.64P–O(d)(2)(A) and (B), if there is Matched Volume, this Auction would result in a trade, otherwise, the series would transition to continuous trading as described in proposed Rule 6.64P–O(f) below.

- If the Market Maker assigned to the series has not submitted a quote with a non-zero offer by the end of the Opening MMQ Time Parameter and there is a Legal Width Quote, the Exchange would conduct the Auction (proposed Rule 6.64P–O(d)(3)(B)(ii)). As set forth in proposed Rule 6.64P–O(d)(2)(A) and (B), if there is Matched Volume, this Auction would result in a trade, otherwise, the series would transition to continuous trading as described in proposed Rule 6.64P–O(f) below.

- Proposed Rule 6.64P–O(d)(3)(C) would provide that if there are two or more Market Makers assigned to a series:

- The Exchange would conduct the Auction, without waiting for the Opening MMQ Time Parameter to end, as soon as there is both a Legal Width Quote and at least two assigned Market Makers have submitted a quote with a non-zero offer (proposed Rule 6.64P–O(d)(3)(C)(i)). As set forth in proposed Rule 6.64P–O(d)(2)(A) and (B), if there is Matched Volume, this Auction would result in a trade, otherwise, the series would transition to continuous trading as described in proposed Rule 6.64P–O(f) below.

- If at least two Market Makers assigned to a series have not submitted a quote with a non-zero offer by the end of the Opening MMQ Time Parameter, the Exchange would begin a second Opening MMQ Time Parameter (of the

same length) and that during the second Opening MMQ Time Parameter, the Exchange would conduct the Auction, without waiting for the second Opening MMQ Time Parameter to end, if there is both a Legal Width Quote and at least one Market Maker assigned to the series has submitted a quote with a non-zero offer (proposed Rule 6.64P–O(d)(3)(C)(ii)). Because the Exchange does not require a Market Maker assigned to a series to quote before conducting an Auction, to reduce the potential delay in opening or reopening a series, the Exchange believes that during the second Opening MMQ Time Parameter, it is appropriate to wait for only one Market Maker, instead of two, to quote. As set forth in proposed Rule 6.64P–O(d)(2)(A) and (B), if there is Matched Volume, this Auction would result in a trade, otherwise, the series would transition to continuous trading as described in proposed Rule 6.64P–O(f) below.

- If no Market Maker assigned to a series has submitted a quote with a non-zero offer by the end of the second Opening MMQ Time Parameter and there is a Legal Width Quote, the Exchange would conduct the Auction (proposed Rule 6.64P–O(d)(3)(C)(iii)). As set forth in proposed Rule 6.64P–O(d)(2)(A) and (B), if there is Matched Volume, this Auction would result in a trade, otherwise, the series would transition to continuous trading as described in proposed Rule 6.64P–O(f) below.

Proposed Rule 6.64P–O(d)(4) would provide that for the first five minutes of the Auction Process (inclusive of the one-minute Opening MMQ Time Parameter(s)), if there is no Legal Width Quote, the Exchange would not conduct an Auction, even if there is Matched Volume, *i.e.*, the series would not transition to continuous trading. This proposed rule text provides transparency that, in the absence of a Legal Width Quote, the Exchange would not conduct an Auction that results in a trade even if there is Matched Volume. In such case, because there is Matched Volume, the Exchange could not open that series and would wait for a Legal Width Quote before conducting the Auction. Consistent with proposed Rule 6.64P–O(d)(2)(A), if at any time during this five-minute period there is a Legal Width Quote, the Exchange would proceed immediately with an Auction and would not wait for the five-minute timer to end.

The Exchange proposes new functionality for Pillar to allow the Exchange to open a series without a trade after five minutes have elapsed without a Legal Width Quote, *i.e.*,

¹⁵⁰ Currently, neither Market Makers nor LMMs are obligated to provide a quote before a series is opened or reopened, which is why the proposed Pillar options Auction rule is designed to provide Market Makers with time to submit their quotes so a series can be opened.

¹⁵¹ A Market Maker may send quotations only in the issues included in its appointment, *i.e.*, in series to which such Market Maker is assigned. See proposed Rule 6.37AP–O(a). See also proposed Rule 6.37AP–O(b) and (c) (setting forth continuous quoting obligations of LMMs and Market Makers, respectively, which obligations are identical to those set forth in Rule 6.37A–O(b) and (c)).

transition to continuous trading as described in proposed Rule 6.64P–O(f), when there is a Calculated NBBO that is wider than the Legal Width Quote. This option to open or reopen a series would not be available if there is Matched Volume. As proposed, five minutes after the Auction Process begins:

- Proposed Rule 6.64P–O(d)(4)(A) would provide that if there is no Matched Volume and the Calculated NBBO is wider than the Legal Width Quote, is not crossed, and does not contain a zero offer, the Exchange would transition to continuous trading as described below in paragraph (f) of this Rule (as described below, a trade could occur during the transition to continuous trading, but there would not be a trade resulting from Matched Volume in the Auction). As further proposed, in such case, the Auction would not be intended to end with a trade, but it may result in a trade (even if there is no Legal Width Quote) if orders or quotes arrive when the Exchange is evaluating the status of orders and quotes, but before the Auction Processing Period begins.¹⁵² The Exchange believes this proposed rule would facilitate the opening or reopening of a series so that it can begin continuous trading when there is a Calculated NBBO in a series that is wider than the Legal Width Quote and is not crossed and does not contain a zero offer.¹⁵³

- Proposed Rule 6.64P–O(d)(4)(A)(i) would provide that any time a series is opened or reopened when there is no Legal Width Quote, *i.e.*, the Auction would end without a trade, Market Orders and MOO Orders would not participate in the Auction and would be cancelled before the Exchange transitions to continuous trading, which would protect such orders from trading at unintended prices.

- Proposed Rule 6.64P–O(d)(4)(B) would provide that if the Exchange still cannot conduct an Auction as provided

under paragraph (A) (above), the Exchange would continue to evaluate both the Calculated NBBO and interest on the Consolidated Book until the earlier of: (i) A Legal Width Quote is established and an Auction can be conducted; (ii) the series can be opened as provided for in proposed Rule 6.64P–O(d)(4)(A); (iii) the series is halted; or (iv) the end of Core Trading Hours. The proposed rule provides transparency that the Exchange would continue to look for an opportunity to open or reopen a series based on changes to the Calculated NBBO or orders and quotes on the Consolidated Book.

Proposed Rule 6.64P–O(d)(5) would provide that the Exchange may deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option series or opening or reopening a series when there is no Legal Width Quote, when it believes it is necessary in the interests of a fair and orderly market. This proposed rule is based on Rule 6.64–O(b)(F) and, consistent with current functionality, is designed to provide the Exchange with flexibility to open a series even if there is no Legal Width Quote.¹⁵⁴ For example, a Floor Broker may have a two-sided open outcry order. If the series is not opened, that trade could not be consummated. Accordingly, this proposed rule would allow the Exchange to open a series for trading to facilitate open outcry trading.

Order Processing during an Auction Processing Period. As described above, the Auction Processing Period is the abbreviated time period (*i.e.*, generally measured in less than a second) when the Exchange conducts the Auction and therefore transitions a series from a pre-open state to continuous trading. For example, if there is a Legal Width Quote, Market Maker quotes, and Matched Volume, the Auction Processing Period is when that Matched Volume will trade at the Indicative Match Price. New orders and quotes received during the Auction Processing Period would not be eligible to participate in that Auction trade. Because the Exchange would be using the same Pillar auction functionality for options trading that is used for its cash equity market, the Exchange proposes that proposed Rule 6.64P–O(e) would be based on Rule 7.35–E(g) and subparagraphs (1) and (2), with differences only to reference quotes in addition to orders. The proposed rule promotes

granularity and transparency of how orders and quotes that arrive during the Auction Processing Period would be processed.

Accordingly, as proposed, new order and quote messages received during the Auction Processing Period would be accepted but would not be processed until after such Auction Processing Period. As with Rule 7.35–E(g), for purposes of proposed Rule 6.64P–O(e) and (f), an “order instruction” would likewise refer to a request to cancel, cancel and replace, or modify an order or quote.

As further proposed, during the Auction Processing Period, order instructions would be processed as follows:

- An order instruction that arrives during the Auction Processing Period would not be processed until after the Auction Processing Period if it relates to an order or quote that was received before the Auction Processing Period. Any subsequent order instructions relating to such order would be rejected (proposed Rule 6.64P–O(e)(1)).

- An order instruction that arrives during the Auction Processing Period would be processed on arrival if it relates to an order that was received during the Auction Processing Period (proposed Rule 6.64P–O(e)(2)).

Transition to Continuous Trading. After the Auction Processing Period concludes, *i.e.*, once the Auction concludes either with or without a trade, the Exchange transitions to continuous trading. During this transition, the way in which orders, quotes, and order instructions are processed would differ depending on when such messages arrived at the Exchange. Proposed Rule 6.64P–O(f) would describe how the Exchange would transition to continuous trading after the Auction Processing Period concludes, which would detail new functionality for options trading under Pillar, and is based on how the Exchange transitions to continuous trading on its cash equity market following an Auction, as described in Rule 7.35–E(h). The Exchange believes that the proposed rule provides granularity regarding how orders and quotes would be processed in connection with the transition to continuous trading for options trading.¹⁵⁵ As proposed, the transition to continuous trading would proceed as follows.

Proposed Rule 6.64P–O(f)(1) would provide that orders that are no longer

¹⁵² The Exchange expects this to be a rare race condition that would result when the Exchange receives orders and quotes at virtually the same time that it is evaluating whether it can open a series on a quote based on a wide Calculated NBBO (and before the Auction Processing Period begins) and that, as a result of that race condition, those new orders or quotes are marketable against contra-side interest, *i.e.*, results in Matched Volume for the Auction, at the same time that the Exchange concludes, based on interest that had previously been received, that it can proceed with an Auction in the absence of a Legal Width Quote. In such case, the Auction could result in a trade.

¹⁵³ Such opening is similar to Cboe’s “Forced Opening” process because it allows a series to open without a trade after a specified time period when the market is wider than the specified bid-ask differentials. See Cboe Rule 5.31(e)(4).

¹⁵⁴ See Rule 6.64–O(b)(F) (providing that “[t]he Exchange may deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option class, when it believes it is necessary in the interests of a fair and orderly market”).

¹⁵⁵ See, *e.g.*, Cboe Rule 5.31(f) (describing Cboe’s process for orders and quotes not executed in its opening process).

eligible to trade would be cancelled. This proposed rule text is based on Pillar terminology used in Rule 7.35–E(h)(1). For options trading, the only orders that would no longer be eligible to trade after the Auction Processing Period concludes would be Auction-Only Orders and such orders would cancel (rather than “expire”).

Proposed Rule 6.64P–O(f)(2) would provide that order instructions would be processed as follows:

- An order instruction that relates to an order or quote that was received before the Auction Processing Period or that has already transitioned to continuous trading and that arrives during either the transition to continuous trading or the Auction Processing Period under paragraph (e)(1) of this Rule would be processed in time sequence with the processing of orders and quotes as specified in paragraphs (f)(3)(A) or (B) of this Rule. In addition, any subsequent order instructions relating to such order or quote would be rejected (proposed Rule 6.64P–O(f)(2)(A)). This proposed rule text is based on Rule 7.35–E(h)(2)(A), except that it does not include reference to order instructions received during an Auction Imbalance Freeze, which, as discussed above, is a concept on the cash equity platform that is not applicable to options trading. This proposed rule text provides transparency regarding how order instructions that arrived during the Auction Processing Period would be processed if they relate to orders or quotes that were received before the Auction Processing Period.¹⁵⁶

- An order instruction that arrives during the transition to continuous trading would be processed on arrival if it relates to an order or quote that was entered during either the Auction Processing Period or the transition to continuous trading and such order or quote has not yet transitioned to continuous trading (proposed Rule 6.64P–O(f)(2)(B)). This proposed rule text is based on Rule 7.35–E(h)(2)(B) without any substantive differences.

Proposed Rule 6.64P–O(f)(3) would set forth how orders and quotes would be processed during the transition to continuous trading following an Auction. The proposed process for transitioning to continuous trading is consistent with current functionality (with differences described below) relating to draining the queue of unexecuted orders and quotes following the current Auction Process. The Exchange believes that the proposed

rule provides granularity of this process as compared to the current Rule. Specifically, the Exchange proposes that it would process Auction-eligible orders and quotes that were received before the Auction Processing Period and orders ranked under the proposed category of “Priority 3- Non-Display Orders” (which interest was not eligible to participate in an Auction) received before a trading halt as follows:

- Proposed Rule 6.64P–O(f)(3)(A)(i) would provide that Limit Orders and quotes would be subject to the Limit Order Price Check, Arbitrage Check, and Intrinsic Value Check, as applicable. This proposed rule differs from current functionality, whereby risk checks are applied before an Auction. This proposed rule text is consistent with the proposed rule changes, described above, regarding when the Limit Order Price Check, Arbitrage Check, and Intrinsic Value Check (per proposed Rules 6.62P–O(a)(3) and 6.41P–O, respectively) would be applied to orders and quotes that were received during a pre-open state. The Exchange proposes to apply these checks to orders and quotes before they become eligible for trading or routing during continuous trading.

- Proposed Rule 6.64P–O(f)(3)(A)(ii) would provide that Limit Orders and Market Orders would be assigned a Trading Collar. This proposed rule is consistent with the proposed changes to Trading Collars on Pillar, described above (per Rule 6.62P(a)(4)), that an order received during a pre-open state would be assigned a Trading Collar after an Auction concludes, or that an order would be reassigned a Trading Collar after a halt.

- Proposed Rule 6.64P–O(f)(3)(A)(iii) would provide that orders eligible to route that are marketable against Away Market Protected Quotations would route based on the ranking of such orders as set forth in Rule 6.76P–O(c). This proposed rule is consistent with current functionality and uses Pillar terminology based on Rule 7.35–E(h)(3)(A)(ii)(a), with differences to use the term “Away Market Protected Quotations” instead of “protected quotations on Away Markets” and to cross reference proposed Rule 6.76P–O(c).¹⁵⁷ As with current functionality, routable orders would be routed to Away Markets to avoid either trading through or locking or crossing an Away Market Protected Quotation.

- Proposed Rule 6.64P–O(f)(3)(A)(iv) would provide that after routing eligible

orders, orders and quotes not eligible to route that are marketable against Away Market Protected Quotations would cancel. This functionality would be new for options trading (such orders and quotes would currently reprice) and this proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(b), with differences to use the term “Away Market Protected Quotations” instead of “protected quotations on Away Markets.” By cancelling non-routable orders and quotes marketable against Away Market Protected Quotations, the Exchange would avoid locking or crossing such Away Market Protected Quotations.

- Proposed Rule 6.64P–O(f)(3)(A)(v) would provide that once there are no more unexecuted orders marketable against Away Market Protected Quotations, orders and quotes that are marketable against other orders and quotes in the Consolidated Book would trade or be repriced. This proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(c), with a difference that an order could be repriced based on this assessment, which would be unique to options trading because as described above, an ALO Order that would be marketable against a contra-side order or quote on the Consolidated Book cannot take liquidity and in such case, the Exchange would reprice an ALO Order that is marketable as provided for in proposed Rule 6.62P–O(e)(2).¹⁵⁸ The Exchange further notes that, similar to the Exchange’s cash equity market, the Exchange could transition to continuous trading without the Auction resulting in a trade, but that a trade(s) may occur during the transition to continuous trading, which trade(s) would be published to OPRA before the Exchange publishes a quote to OPRA.¹⁵⁹ The Exchange would not consider a trade that occurs during the transition to continuous trading to be an Auction that results in a trade.¹⁶⁰

¹⁵⁸ As described above, the Exchange proposes a difference on Pillar because ALO Orders would be eligible to participate in an Auction. Currently, ALOs will be rejected if entered outside of Core Trading Hours or during a trading halt or, if resting, will be cancelled in the event of a trading halt. See discussion *supra* regarding Rule 6.62–O(t).

¹⁵⁹ For example, the Exchange may determine that, as described in proposed Rule 6.64P–O(d)(4)(A), if there is no Matched Volume but there is a Calculated NBBO that meets the requirements specified in that Rule, it can conduct an Auction without a trade and transition to continuous trading pursuant to proposed Rule 6.64P–O(f). In such case, there would not be an Auction that results in a trade, but a trade(s) could occur among orders and quotes that trade during the transition to continuous trading.

¹⁶⁰ OPRA does not distinguish between a trade that results from an opening auction and a trade that occurs during the transition to continuous trading. By contrast, the Exchange’s proprietary data feed would distinguish a trade that resulted

¹⁵⁶ See *id.* (unexecuted orders and quotes will be entered into the Cboe book in time sequence).

¹⁵⁷ See *supra* note 95 (citing definitions of “Protected Bid,” “Protected Offer,” and “Quotation” set forth in in Rule 6.92–O(a)(15) and (16) and of “Away Market” as set forth in proposed Rule 1.1).

- Proposed Rule 6.64P–O(f)(3)(A)(vi) would provide that Market Orders received during a pre-open state would be subject to the validation specified in proposed Rule 6.62P–O(a)(1)(C). The Exchange notes that because such Market Orders would already have been received by the Exchange, if such orders fail one of those validations, they would be cancelled instead of rejected. This would be new rule text as compared to the Exchange’s cash equity rules to reflect the validations that would be applicable to Market Orders for options trading on Pillar and would add transparency and granularity to Exchange rules.

- Proposed Rule 6.64P–O(f)(3)(A)(vii) would provide that the display quantity of Reserve Orders would be replenished. This proposed rule is based on Rule 7.35–E(h)(3)(A)(ii)(d), without any substantive differences. This proposed rule is based on current functionality and provides granularity in Exchange rules.

- Proposed Rule 6.64P–O(f)(3)(A)(viii) would describe the last step in this process regarding Auction-eligible interest received before the Auction Processing Period and orders ranked under the proposed category of “Priority 3—Non-Display Orders” received before a trading halt. Specifically, the Exchange would send a quote to OPRA and proprietary data feeds representing the highest-priced bid and lowest-priced offer of any remaining, unexecuted Auction-eligible orders and quotes that were received before the Auction Processing Period. This proposed rule is consistent with current options functionality and is also based on current cash equity functionality, as set forth in Rule 7.35–E(h)(3)(A)(ii). Although the functionality would be the same for both markets, for options traded on the Exchange, the Exchange proposes to describe this aspect of the process in sequence, and reference both orders and quotes. The Exchange notes that this quote sent to OPRA would be different than the Rotational Quote sent at the beginning of the Auction Process because it could be comprised of both orders and quotes. At a high level, this represents current functionality because after a series opens, the Exchange disseminates its best bid and offer of its quotes and orders to OPRA.

- Proposed Rule 6.64P–O(f)(3)(B) would provide that next, orders ranked under the proposed category of “Priority 3—Non-Display Orders” that were received during a pre-open state would be

assigned a new working time, in time sequence relative to one another based on original entry time, and would be subject to the Limit Order Price Check, Arbitrage Check, and Intrinsic Value Check, as applicable, and if not cancelled, would be traded or repriced. This proposed functionality would be new for Pillar and applicable only for options traded on the Exchange. Even though orders ranked Priority 3—Non-Display Orders would not be eligible to trade in an Auction (other than the reserve interest of Reserve Orders), the Exchange proposes to accept such orders during a pre-open state. These orders would transition to continuous trading after any unexecuted Auction-eligible interest transitions to continuous trading, as described above in proposed Rule 6.64P–O(f)(3)(A)(i)—(viii). The Exchange believes that waiting to process non-displayed orders in this sequence would ensure that there is an NBBO against which such orders could be priced, as described in proposed Rule 6.62P–O(d) (regarding Orders with a Conditional or Undisplayed Price and/or Size) above.

Proposed Rule 6.64P–O(f)(3)(C) would provide that next, orders and quotes that were received during the Auction Processing Period would be assigned a new working time in time sequence relative to one another, based on original entry time and would be subject to the Limit Order Price Check, Pre-Trade Risk Controls, Arbitrage Check, Intrinsic Value Check, and validations specified in proposed Rule 6.62P–O(a)(1)(A), as applicable to certain Market Orders, and if not cancelled would be processed consistent with the terms of the order or quote. This proposed rule text is designed to reflect that orders and quotes received during the Auction Processing Period would not be subjected to these price/risk validations until after the Exchange has transitioned to continuous trading, and that if such interest fails these validations, those orders or quotes would be cancelled instead of rejected. This proposed rule text is based on Rule 7.35–E(h)(3)(B), with differences to reflect the price/risk validations that would be applicable to orders and quotes for options trading.

Proposed Rule 6.64P–O(f)(3)(D) would further provide that when transitioning to continuous trading:

- The display price and working price of orders and quotes would be adjusted based on the contra-side interest in the Consolidated Book or Away Market NBBO, as provided for in Rule 6.62P–O (proposed Rule 6.64P–O(f)(3)(D)(i)). This proposed rule is based on Rule 7.35–E(h)(3)(C), with

differences to reflect that, for options trading, the display price or working price of an order may be adjusted based either on contra-side interest on the Consolidated Book (e.g., for ALO Orders) or the Away Market NBBO (as opposed to the PBBO or NBBO for cash equities trading).

- The display price and working price of a Day ISO would be adjusted in the same manner as a Non-Routable Limit Order until the Day ISO is either traded in full or displayed at its limit price and the display price and working price of a Day ISO ALO would be adjusted in the same manner as an ALO Order until the Day ISO ALO is either traded in full or displayed at its limit price (proposed Rule 6.64P–O(f)(3)(D)(ii)). This proposed rule is new for options trading because, as described above, the Exchange would be offering Day ISO and Day ISO ALO for options trading for the first time with the transition to Pillar. The rule text is based in part on Rule 7.35–E(h)(3)(D), with differences to reflect how a Day ISO ALO would be processed on options as compared to how similarly-named orders trade on the Exchange’s cash equity market, as described in more detail above in connection with proposed Rule 6.62P–O(e)(3).

Proposed Rule 6.64P–O(g) would describe order processing during a trading halt. The proposed rule is based in part on Rule 7.18–E(c), with differences to reflect how options would trade on Pillar as described below. The proposed Rule is designed to provide granularity in Exchange rules about how new and existing orders, quotes, and order instructions would be processed during a trading halt. As proposed, the Exchange would process new and existing orders and quotes in a series during a trading halt as follows:

- Cancel any unexecuted quantity of orders for which the 500-millisecond Trading Collar timer has started and all resting Market Maker quotes (proposed Rule 6.64P–O(g)(1)). This proposed rule would be unique for options traded on the Exchange. The Exchange proposes to cancel resting Market Maker quotes when a trading halt is triggered, which represents current functionality, and as noted below, would accept new Market Maker quotes during a trading halt, which would be the basis for the Rotational Quote that would be published for a Trading Halt Auction. The Exchange also proposes to cancel any unexecuted quantity of orders for which the 500-millisecond Trading Collar has started because such timer would have ended during a trading halt, and therefore such orders were subject to cancellation already. This would be

from an Auction from a trade that occurred during the transition to continuous trading.

new functionality on Pillar and reflects the proposed new Trading Collar behavior that orders would be priced at their collar for only 500 milliseconds and then would cancel.

- Re-price all other resting orders on the Consolidated Book to their limit price. This would be new functionality on Pillar for options trading; currently, during a halt, resting orders do not reprice to their limit price.¹⁶¹ The repricing of a Non-Routable Limit Order, ALO Order, or Day ISO ALO to its limit price during a trading halt would not be counted toward the (limited) number of times such order may be repriced, and any subsequent repricing of such order during the transition to continuous trading would be permitted as the additional (unaccounted) repricing event as provided for in proposed Rules 6.62P–O(e)(1)(B) and (e)(2)(C) (proposed Rule 6.64P–O(g)(2)). As described above, once resting, a Non-Routable Limit Order, ALO Order, or Day ISO ALO that was repriced on arrival is eligible to be repriced only one additional time. This proposed rule provides transparency that the repricing of such orders to their limit price during a trading halt would not count towards that “one” additional repricing, but that any subsequent repricing after the Auction concludes would count.

- Accept and process all cancellations (proposed Rule 6.64P–O(g)(3)). This proposed rule is based on Rule 7.18–E(c)(4), without any differences, and is consistent with current functionality.

- Reject incoming Limit Orders designated IOC or FOK (proposed Rule 6.64P–O(g)(4)). This proposed rule is based on Rule 7.18–E(c)(5), with a difference to add orders designated FOK and not include non-displayed orders and is consistent with current functionality.

- Accept all other incoming order and quote messages and instructions until the Auction Processing Period for the Trading Halt Auction ends, at which point, paragraph (e) of proposed Rule 6.64P–O would govern the entry of incoming orders, quotes, and order instructions (proposed Rule 6.64P–O(g)(5)). This proposed rule is based on Rule 7.18–E(c)(6), with differences to cross reference the options rule relating to the transition to continuous trading and is consistent with current functionality.

- Disseminate a zero bid and zero offer quote to OPRA and proprietary

data feeds (proposed Rule 6.64P–O(g)(6)). This proposed rule is based on current functionality and is designed to promote clarity and transparency in Exchange rules that when a trading halt begins, the Exchange will “zero” out the Exchange’s BBO.

Finally, proposed Rule 6.64P–O(h) would provide that whenever, in the judgment of the Exchange, the interests of a fair and orderly market so require, the Exchange may adjust the timing of or suspend the Auctions set forth in this Rule with prior notice to OTP Holders and OTP Firms. This proposed rule is based on Rule 7.35–E(i), with a difference to reference OTP Holders instead of ETP Holders and also reference OTP Holders and OTP Firms.

In connection with proposed Rule 6.64P–O, the Exchange proposes to add the following preamble to Rule 6.64–O: “This Rule is not applicable to trading on Pillar.” This proposed preamble is designed to promote clarity and transparency in Exchange rules that Rule 6.64–O would not be applicable to trading on Pillar.

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As discussed above, because of the technology changes associated with the migration to the Pillar trading platform, subject to approval of this proposed rule change, the Exchange will announce by Trader Update when rules with a “P” modifier will become operative and for which symbols. The Exchange believes that keeping existing rules on the rulebook pending the full migration of Pillar will reduce confusion because it will ensure that the rules governing trading on the OX system will continue to be available pending the full migration to Pillar.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”),¹⁶² in general, and furthers the objectives of Section 6(b)(5),¹⁶³ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rules to support Pillar would remove impediments to and perfect the mechanism of a free and

open market and a national market system because the proposed rules would promote transparency in Exchange rules by using consistent terminology governing trading on both the Exchange’s cash equity and options trading platforms, thereby ensuring that members, regulators, and the public can more easily navigate the Exchange’s rulebook and better understand how options trading is conducted on the Exchange.

Generally, the Exchange believes that adding new rules with the modifier “P” to denote those rules that would be operative for the Pillar trading platform would remove impediments to and perfect the mechanism of a free and open market and a national market system by providing transparency of which rules would govern trading once a symbol has been migrated to the Pillar platform. The Exchange similarly believes that adding a preamble to those current rules that would not be applicable to trading on Pillar would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote transparency regarding which rules would govern trading on the Exchange during and after the transition to Pillar.

In addition, the Exchange believes that incorporating functionality currently available on the Exchange’s cash equity market for options trading would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Exchange would be able to offer consistent functionality across both its options and cash equity trading platforms, adapted as applicable for options trading. Accordingly, with the transition to Pillar, the Exchange will be able to offer additional features to its OTP Holders and OTP Firms that are currently available only on the Exchange’s cash equity platform. For similar reasons, the Exchange believes that using Pillar terminology for the proposed new rules would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote consistency in the Exchange’s rules across both its options and cash equity platforms.

Definitions and Applicability

The Exchange believes that the proposed amendments to Rule 1.1, including adding definitions from Rule 6.1–O and Rule 6.1A–O to Rule 1.1, would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed changes

¹⁶¹ On its cash equities market, for trading halts in Exchange-listed securities, the Exchange reprices resting orders to their limit price. See Rule 7.18–E(c)(3).

¹⁶² 15 U.S.C. 78f(b).

¹⁶³ 15 U.S.C. 78f(b)(5).

are designed to promote clarity and transparency in Exchange rules by consolidating into Rule 1.1 definitions relating to both cash equity and options trading. The Exchange believes that the proposed changes to eliminate obsolete definitions and modifying the text of certain existing definitions relating to options trading that are being added to Rule 1.1, would further remove impediments to and perfect the mechanism of a free and open market and a national market system because it would ensure that the definitions used in Exchange rules are updated and consistent. Finally, the Exchange believes that organizing Rule 1.1 alphabetically and eliminating subparagraph numbering would make the proposed rules easier to navigate.

The Exchange further believes that proposed new Rule 6.1P-O relating to applicability would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule would include those elements of current Rule 6.1-O that would remain applicable and eliminates duplicative text that would no longer be necessary after the transition to Pillar. The Exchange further notes that proposed Rule 6.1P-O is similar to NYSE American Rule 900.1NY.

Order Ranking and Display

The Exchange believes that proposed new Rule 6.76P-O would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Exchange is not proposing substantive changes to how the Exchange would rank and display orders and quotes on Pillar as compared to the OX system. Rather, the proposed revisions to the Exchange's options trading rules would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed changes are designed to simplify the structure of the Exchange's options rules and use consistent Pillar terminology for both cash equity and options trading, without changing the underlying functionality for options trading. For example, the Exchange believes the proposed definitions set forth in Rule 6.76P-O, *i.e.*, display price, limit price, working price, working time, and Aggressing Order/Aggressing Quote, would promote transparency in Exchange rules and make them easier to navigate because these proposed definitions would be used in other proposed Pillar options trading rules. The Exchange notes that these proposed definitions are

consistent with the definitions set forth in Rule 7.36-E for cash equity trading with differences only as necessary to address functionality associated with options trading that are not applicable to cash equity trading, *e.g.*, reference to quotes.

The Exchange further believes that moving descriptions of order type behavior, which are currently set forth in Rule 6.76-O, to proposed Rule 6.62P-O, and therefore not include such detail in proposed Rule 6.76P-O, would make Exchange rules easier to navigate because information regarding how a specific order type would operate would be in a single location in the Exchange's rulebook. The Exchange notes that this proposed structure is consistent with the Exchange's cash equity rules, which similarly set forth information relating to an order type's ranking in Rule 7.31-E.

Moreover, the Exchange is not proposing any functional changes to how it would rank and display orders and quotes on Pillar as compared to the OX system. Rather, the Exchange believes that using new terminology to describe ranking and display, including the proposed priority categories of Priority 1—Market Orders, Priority 2—Display Orders, and Priority 3—Non-Display Orders, would remove impediments and perfect the mechanism of a free and open market and a national market system because the proposed rule would provide more granularity and use Pillar terminology to describe functionality that is consistent with the OX system functionality currently referred to as the "Display Order Process" and the "Working Order Process" in Rule 6.76-O.

Order Execution and Routing

The Exchange believes that proposed new Rule 6.76AP-O would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule would set forth a price-time priority model for Pillar that is substantively the same as the Exchange's current price-time priority model as set forth in Rule 6.76A-O. The proposed differences as compared to Rule 6.76A-O are designed to use Pillar terminology that is based in part on Rule 7.37-E, if applicable, without changing the functionality that is currently available for options trading.

The Exchange believes that the proposed modifications to the LMM Guarantee would remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides clarity of how multiple quotes from an LMM

would be allocated (*i.e.*, only the first quote in time priority would be eligible for the LMM Guarantee). The Exchange similarly believes that eliminating Directed Order Market Makers and Directed Orders would remove impediments to and perfect the mechanism of a free and open market and a national market system because these features are not currently used on the Exchange, and therefore eliminating Directed Orders and Directed Order Market Makers would streamline the Exchange's rules. The Exchange notes that the remaining differences in proposed Rule 6.76AP-O relating to the LMM Guarantee are designed to promote clarity and transparency in Exchange rules and would not introduce new functionality.

The Exchange believes that the structure and content of the rule text in proposed Rule 6.76AP-O promotes transparency by using consistent Pillar terminology. The Exchange also believes that adding more detail regarding current functionality in new Rule 6.76AP-O, as described above, would promote transparency by providing notice of when orders would be executed or routed by the Exchange.

Orders and Modifiers

The Exchange believes that proposed new Rule 6.62P-O would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would use existing Pillar terminology to describe the order types and modifiers that would be available on the Exchange's options Pillar trading system. As noted above, the Exchange proposes to offer order types and modifiers that are either based on existing order types available on the OX system as described in Rule 6.62-O, or orders and modifiers available on the Exchange's cash equity trading platform, as described in Rule 7.31-E, with differences as applicable to reflect differences in options trading from cash equity trading. The Exchange believes that structuring proposed Rule 6.62P-O based on the structure of Rule 7.31-E would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote transparency and consistency in the Exchange's rulebook.

In addition to the terminology changes to describe the order types and modifiers that are currently available on the Exchange, the Exchange further believes that the order types and modifiers proposed for options trading on Pillar that either differ from order types and modifiers available on the OX

system or that would be new would remove impediments to and perfect the mechanism of a free and open market and national market system because:

- Market Orders on Pillar would function similarly to how Market Orders function under current options trading rules, including being subject to Trading Collars. However, the proposed functionality would expand the circumstances under which Market Orders may be rejected, which functionality is designed to ensure that Market Orders do not execute either when there is no prevailing market in a series, which can occur if there is no NBO, no NBB and an NBO higher than \$0.50, or an absence of contra-side Market Maker quotations or an Away Market NBBO. In addition, the proposed functionality would provide that if the displayed prices are too wide to assure a fair and orderly execution of a Market Order, such Market Order would be rejected. The Exchange believes that the proposed “wide-spread” check for Market Orders is consistent with similar price protections on other options exchanges and is designed to prevent a Market Order trading at a price that could be considered a Catastrophic Error.¹⁶⁴ The Exchange believes that the proposed rule describing Market Orders would promote transparency by providing notice of when a Market Order would be subject to such validations.

- The Exchange is not proposing any new or different behavior for Limit Orders than is currently available for options trading on the Exchange, other than the application of Limit Order Price Protection and Trading Collars, which would differ on Pillar. The Exchange believes using Pillar terminology based on Rule 7.31–E(a)(2) to describe Limit Orders would promote consistency and clarity in Exchange rules.

- The proposed Limit Order Price Protection functionality is based in part on the existing “Limit Order Filter” for orders and price protection filters for quotes because an order or quote would be rejected if it is priced a specified percentage away from the contra-side NBB or NBO. The proposed Limit Order Price Protection functionality is also based in part on the functionality available on the Exchange’s cash equity trading platform, and therefore is not novel. The Exchange believes that using the same mechanism for both orders and quotes would simplify the operation of

the Exchange and achieve similar results as the current rules, which is to reject an order or quote that is priced too far away from the prevailing market. The Exchange believes that re-applying Limit Order Price Protection after an Auction concludes would ensure that Limit Orders and quotes continue to be priced consistent with the prevailing market, and that using an Auction Price (if available, and if not available, Auction Collars, and if not available, the NBBO) to assess Limit Orders and quotes after an Auction concludes would ensure that the Exchange would be applying the most recent price in a series in assessing whether such orders or quotes should be cancelled. The Exchange further believes that the proposed Specified Thresholds for determining whether to reject a Limit Order or quote would remove impediments to and perfect the mechanism of a free and open market and a national market system because they are designed to be tailored to the applicable Reference Price, and thus more granular than the current thresholds.

The proposed Trading Collar functionality is based in part on how trading collars currently function on the Exchange because the proposed functionality would create a ceiling or floor price at which an order could be traded or routed. The Exchange believes that the proposed differences for Trading Collars on Pillar, including applying the same Trading Collar logic to both Limit Orders and Market Orders, applying them once per trading day (unless there is a trading halt), tailoring the specified thresholds to be within the current parameters for determining whether a trade would be an Obvious Error or Catastrophic Error, and canceling orders that have been displayed at their Trading Collar for 500 milliseconds, would remove impediments to and perfect the mechanism of a free and open market and a national market system because they are designed to provide a deterministic price protection mechanism for orders. In addition, the proposed Pillar Trading Collar functionality is designed to simplify the process by applying a static ceiling price (for buy orders) or floor price (for sell orders) at which such order could be traded or routed that would be applicable to the order until it is traded or cancelled. The Exchange believes that the proposed functionality would provide greater determinism to an OTP Holder or OTP Firm of the Trading Collar that would be applicable to its

orders and when such orders may be cancelled if it reaches its Trading Collar.

- The Exchange is not proposing any new or different Time-in-Force modifiers than are currently available for options trading on the Exchange. The Exchange believes using Pillar terminology based on Rule 7.31–E(b) to describe the time-in-force modifiers would promote consistency and clarity in Exchange rules.

- Auction-Only Orders, and specifically, the proposed MOO and LOO Orders, would operate no differently than how “Opening-Only Orders” currently function on the OX system. However, rather than refer to Opening-Only Orders, the Exchange proposes to use Pillar terminology that is based on Rule 7.31–E(c) terminology. The Exchange further believes that offering its IO Order type for Auctions on the options trading platform—both for Core Open Auctions and Trading Halt Auctions—would provide OTP Holders and OTP Firms with new, optional functionality to offset an Imbalance in an Auction. The proposed availability of the IO Order on the options platform would be more expansive than is currently available on the Exchange’s cash equity platform, which (unlike options) does not account for quotes in determining an Imbalance and which limits the use of IO Orders solely to Trading Halt Auctions. The Exchange believes this proposed functionality would afford OTP Holders and OTP Firms with greater flexibility for all Auctions on Pillar.

- The Exchange would continue to offer Reserve Orders, AON Orders, Stop Orders, and Stop Limit Orders, which are currently available on the OX system. The proposed differences to Reserve Orders for options trading would harmonize with how Reserve Orders function on the Exchange’s cash equity market, with changes as applicable to address options trading (e.g., no round lot/odd lot concept for options trading). The proposed changes to AON Orders would provide greater execution opportunities for such orders by allowing them to be integrated in the Consolidated Book and once resting, trade with incoming orders and quotes. The changes are also based on how orders with an MTS Modifier, which are also conditional orders, function on the Exchange’s cash equity market. The Exchange believes it is appropriate to opt not to support Market Orders designated as AON on Pillar because such functionality was not used often on the OX system, indicating a lack of market participant interest in this functionality. The proposed differences for Stop Orders and Stop Limit Orders

¹⁶⁴ See *supra* note 55 (citing Cboe’s Market Order NBBO Width Protection, which similarly looks to the midpoint of the NBBO in applying this protection).

are designed to promote transparency by providing clarity of circumstances when either order may be elected and make clear that, once elected, such orders are subject to the price protection and risk checks applicable to Market Orders and Limit Orders, respectively. Finally, the Exchange believes that offering Non-Displayed Limit Orders for options trading on Pillar, which are available on the Exchange's cash equity platform, would provide additional, optional trading functionality for OTP Holders and OTP Firms. The Exchange notes that the proposed Non-Displayed Limit Order would function similarly to how a PNP Blind Order that locks or crosses the contra-side NBBO would be processed because in such circumstances, a PNP Blind Order is not displayed. A Non-Displayed Limit Order would differ from a PNP Blind Order only because it would never be displayed, even if its limit price doesn't lock or cross the contra-side NBBO.

- The Exchange believes that the proposed orders (and quotes) with instructions not to route (*i.e.*, Non-Routable Limit Order, ALO Order, and ISOs) would streamline the offerings available for options trading on the Exchange by making the functionality the same for both orders and quotes and consolidating the description of non-routable orders and quotes in proposed Rule 6.62P-O(e). In particular, the Exchange believes that allowing Market Makers to enter a Non-Routable Limit Order or an ALO Order and then opt to designate such as either as a quote or an order would streamline Exchange rules by consolidating the description of the functionality in a single rule, thereby adding clarity and transparency. The Exchange believes that using Pillar terminology, including order type names, that is based on the terminology used for cash equity trading would promote clarity and consistency across the Exchange's cash equity and options trading platforms.

The Exchange believes that the proposed Non-Routable Limit Order is not novel because it is based on how the PNP, RPNP, and MMRP orders and quotes currently function on the OX system, including the continued availability of the option to designate a non-routable order either to cancel or reprice if it is marketable against an Away Market NBBO. The Exchange believes that the proposed differences (which would be new for options trading and are not currently available on the Exchange's cash equity market) would provide OTP Holders and OTP Firms with greater determinism of when such orders or quotes may be repriced by limiting the number of times a

resting order could be repriced. The Exchange further believes that providing additional options to cancel a resting Non-Routable Limit Order or ALO Order rather than reprice an additional time would provide additional choice to market participants. Similarly, the proposed ALO Order is not novel because it is based in part on how the RALO and MMLO orders and quotes currently function on the OX system. As such, the Exchange believes that the proposed non-routable order/quote types would continue to provide OTP Holders and OTP Firms with the core functionality associated with existing non-routable order/quote types that would not be offered under Pillar, including that the proposed rules would provide for non-routable functionality and the ability to either reprice or cancel such orders/quotes. The Exchange believes the proposed functionality to allow an ALO Order (which can never be a liquidity taker) to lock non-displayed interest (which is consistent with the treatment of ALO Orders on the Exchange's cash equity platform) or to reprice if such order crosses non-displayed interest, would reduce potential repricing or cancellation events for an incoming ALO Order and would likewise reduce potential information leakage about non-displayed interest in the Consolidated Book.

Finally, the proposed IOC ISO is not novel for options trading on the Exchange and the Exchange believes that the proposed Pillar terminology to describe the same functionality would promote transparency. The proposed DAY ISO and DAY ISO ALO functionality would be new for options trading and are based in part on how such order types function in the Exchange's cash equity market. In addition, the proposed DAY ISO functionality is consistent with existing Rule 6.95-O(b)(3), which currently provides an exception to locking or crossing an Away Market Protected Quotation if the OTP Holder or OTP Firm simultaneously routed an ISO to execute against the full displayed size of any locked or crossed Protected Bid or Protected Offer. The Exchange notes that this exception is not necessary for IOC ISOs because such orders would never be displayed at a price that would lock or cross a Protected Quotation; they cancel if they cannot trade. Accordingly, this existing exception in the Exchange's rules contemplates an ISO that would be displayed, which would mean it would need a time-in-force modifier of "Day." In addition, Day ISOs are available for options trading on

other options exchanges, and therefore are not novel.¹⁶⁵

- The Exchange believes that the proposed additional detail defining Complex Orders to define the "legs" and "components" of such orders would promote transparency in Exchange rules.

- On Pillar, the only electronically-entered crossing orders would be QCC Orders, which is consistent with current functionality. The Exchange believes that the proposed differences, including using Pillar terminology and consolidating rule text relating to QCC Orders in proposed Rule 6.62P-O, would promote transparency and clarity in Exchange rules. In addition, the Exchange believes that the proposed descriptions of how a QCC Order priced at the market would be traded, including the proposed new functionality, would provide transparency regarding at which price such orders would trade. The proposed description of Complex Cross Orders, including Complex QCCs, is designed to distinguish such orders from Single-Leg Cross Orders and to promote clarity and transparency in Exchange rules regarding the price requirements for a Complex Cross Order, including when there is no NBB or NBO on a given leg or there is displayed Customer interest equal to the best-priced complex interest. Further, Complex QCC (which, at this time, are the only electronic Complex Cross Orders to be offered under Pillar) are available for trading on other options exchanges, and therefore are not novel.¹⁶⁶

- The Exchange believes that moving the descriptions of orders available only in open outcry from Rule 6.62-O to proposed Rule 6.62P-O(h) would ensure that these order types remain in the rulebook after the transition to Pillar is complete. For CTB Orders, the Exchange believes that, because Floor Brokers have an existing obligation to satisfy better-priced interest on the Consolidated Book, the proposed change to automate such priority on Pillar (*i.e.*, to allow CTB Orders to satisfy any displayed interest (including non-Customer interest) at better prices than the latest-arriving displayed Customer interest) would not only make it easier for Floor Brokers to comply with Exchange priority rules, but would also increase execution opportunities and achieve the goal of a CTB Order. The Exchange also believes that codifying this order type and the

¹⁶⁵ See *supra* notes 96, 97 (citing to availability of Day ISO orders on Nasdaq and Cboe).

¹⁶⁶ See *supra* note 102 (citing Complex QCC Order type, as offered on Cboe and ISE).

associated regulatory obligations would add clarity and transparency in Exchange rules.

- The proposed Proactive if Locked/ Crossed Modifier, STP Modifier, and MTS Modifier are not novel and are based on the Exchange's current cash equity modifiers of the same name. The Exchange believes that extending the availability of these existing modifiers to options trading would provide OTP Holders and OTP Firms with additional, optional functionality that is not novel and is based on existing Exchange rules. Further, such proposed optional functionality would afford OTP Holders and OTP Firms with greater flexibility in specifying how their trading interest should be handled. For example, the proposed MTS Modifier works similarly to the existing (and proposed) AON functionality, but provides the OTP Holder or OTP Firm with the alternative to designate a portion smaller than the full quantity as the minimum trade size. The Exchange further believes that extending the availability of STP Modifiers to all orders and quotes, and not just those of Market Makers, would provide additional protections for OTP Holders and OTP Firms and facilitate their compliance and risk management by assisting them in avoiding unintentional wash-sale trading.

Market Maker Quotations

The Exchange believes that proposed Rule 6.37AP-O would remove impediments to and perfect the mechanism of a free and open market and a national market system because it is based on current Rule 6.37A-O, with such changes as necessary to use Pillar terminology. The Exchange believes that consolidating into one rule functionality for orders and quotes, such that Non-Routable Limit Orders and ALO Orders may be designated as quotes per proposed Rule 6.37AP-O, would obviate the need to separately describe the same functionality in two rules and therefore streamline the Exchange's rules and promote transparency and consistency.

Pre-Trade and Activity-Based Risk Controls

The Exchange believes that the proposed Rule 6.40P-O, setting forth pre-trade and activity-based risk controls, would remove impediments to and perfect the mechanism of a free and open market and a national market system and promote just and equitable principles of trade because the proposed functionality would incorporate existing activity-based risk controls, without any substantive differences, and augment them with additional pre-trade risk

controls and related functionality that are based on the pre-trade risk controls currently available on the Exchange's cash equity trading platform. The Exchange believes that the proposed differences are designed to provide greater flexibility to OTP Holders and OTP Firms in how to set risk controls for both orders and quotes. The Exchange believes that using Pillar terminology based on the cash equity rules, including using the term "Entering Firm" to mean OTP Holders and OTP Firms, including Market Makers, would promote transparency in Exchange rules. In addition, the proposed Single Order Maximum Notional Value Risk Limit and Single Order Maximum Quantity Risk Limit checks would provide Entering Firms with additional risk protection mechanisms on an individual order or quote basis. Moreover, the Exchange believes that aggregating a Market Maker's quotes and orders for purposes of calculating activity-based risk controls would better reflect the aggregate risk that a Market Maker has with respect to its quotes and orders. The Exchange further believes that the proposed Automated Breach Actions would provide Entering Firms with additional flexibility in how they could set their risk mechanisms and the automated responses if a risk mechanism is breached. The proposed Kill Switch Action functionality would also provide OTP Holders and OTP Firms with greater flexibility to provide bulk instructions to the Exchange with respect to cancelling existing orders and quotes and blocking new orders and quotes. Further, as noted herein, providing "Kill Switch Action" functionality in Exchange rules is consistent with the rules of other options exchanges.¹⁶⁷

Price Reasonability Checks—Orders and Quotes

The Exchange believes that the proposed Rule 6.41P-O, setting forth Price Reasonability Checks, would remove impediments to and perfect the mechanism of a free and open market and a national market system because they are based on existing functionality, with differences designed to use Pillar terminology and promote consistency and transparency in Exchange rules. Specifically, on Pillar, the Exchange proposes to apply the same types of Price Reasonability Checks to both orders and quotes, and therefore proposes to describe those checks in a single rule—proposed Rule 6.41P-O.

The proposed rule also provides specificity regarding when the Price Reasonability Checks would be applied to an order or quote, which would promote transparency and clarity in Exchange rules. In addition, the Exchange believes that by utilizing the last sale on the Primary Market (rather than the Consolidated Last Sale) for the Price Reasonability Checks, the Pillar system would need to ingest and process less data, thereby improving efficiency and performance of the system without compromising the price protection features.

Auction Process

The Exchange believes that proposed Rule 6.64P-O would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule maintains the fundamentals of an auction process that is tailored for options trading while at the same time enhancing the process by incorporating certain Pillar auction functionality that is currently available on the Exchange's cash equity platform, as described in Rule 7.35-E. For example, the Exchange proposes to augment the imbalance information that would be disseminated in advance of an Auction to include fields available on the Exchange's cash equity market (e.g., Book Clearing Price, Far Clearing Price, Auction Collars, and Auction Indicators), yet tailor such information to be specific to options trading (e.g., Auction Collars based on a Legal Width Quote and how the Auction Indicator would be determined). The Exchange believes that the proposed additional Auction Imbalance Information would promote transparency to market participants in advance of an Auction. The Exchange also proposes to transition to continuous trading following an Auction in a manner similar to how the Exchange's cash equity market transitions to continuous trading following a cash equity Trading Halt Auction, including how orders and quotes that are received during an Auction Processing Period would be processed, which the Exchange believes would promote consistency across the Exchange's options and cash equity trading platforms. The proposed rule describing how orders and quotes that are received during the Auction Processing Period would be handled, and how unexecuted quotes and orders would be transitioned to continuous trading would provide granularity regarding the process, thereby providing transparency in Exchange rules. Because the Exchange would be harnessing Pillar technology to support Auctions for

¹⁶⁷ See *supra* note 115 (citing optional "Kill Switch" functionality available on Cboe).

options trading, the Exchange believes that structuring proposed Rule 6.64P–O based on Rule 7.35–E (and NYSE Rule 7.35, in part, as well) would promote transparency in the Exchange’s trading rules.

The Exchange further believes that the proposed Auction Process for options trading on Pillar would remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed process maintains the core functionality of the current options auction process, including that orders are matched based on price-time priority and that an Auction would not be conducted if the bid-ask differential is not within an acceptable range. As proposed, the Auction Process on Pillar would begin with the proposed Rotational Quote, which would provide notice not only of when the process would begin, but also whether Market Makers on the Exchange have quoted in a series. Similar to the current rule, the Exchange would require a “Calculated NBBO,” which is calculated using information consistent with the information the Exchange receives from OPRA before the Exchange opens a series, to meet specified requirements, including that it not be crossed, not have a zero offer, and meet specified bid-ask differentials, *i.e.*, be a “Legal Width Quote” before a series can be opened with a trade.¹⁶⁸ The Exchange believes that the proposed bid-ask differentials for a Legal Width Quote are consistent with current functionality, with one difference designed to improve the automated implementation by using whole dollar amounts as the break point for the next level of bid-ask differentials. In addition, the Exchange believes that the proposed Auction Trigger, which would begin the Auction Process, is consistent with the current trigger for starting an auction. The Exchange believes that the proposed difference to allow the trade on the Primary Market to be odd-lot sized (in addition to having a quote from the Primary Market, which means that the underlying security would be open on the Primary Market), would allow for series overlaying low-volume securities to open automatically and reduce the need to manually trigger an Auction in a series.

As with the current rule, Market Makers are not obligated to quote in their assigned series for an Auction. However, the Exchange believes that

having Market Makers quote in their assigned series would promote fair and orderly Auctions. Accordingly, the Exchange proposes a difference on Pillar to provide time for Market Maker(s) assigned to a series to enter quotes within the specified bid-ask differentials before a series could be opened or reopened. The proposed Opening MMQ Time Parameter would be a minute, and the proposed rule provides transparency of how many Market Makers assigned to a series would be required to quote in a series and in what time periods. If Market Makers do not quote within those specified time periods, but at the end of the Opening MMQ Time Parameter there is a Legal Width Quote based on the Away Market NBBO, the Exchange would open or reopen that series for trading. The Exchange believes that the proposed rule would promote transparency in Exchange rules of when the Exchange could open or reopen a series, including circumstances of when the Exchange would wait to provide Market Makers time to submit a two-sided quotation in a series and when the Exchange would proceed with opening or reopening a series based on a Legal Width Quote even if there are no Market Maker quotes in that series.

The proposed rule would also provide transparency of when the Exchange would open or reopen a series for trading when the Calculated NBBO is wider than the Legal Width Quote for the series. The Exchange believes that the proposed process is designed to provide additional opportunities for a series to open or reopen not currently available on the OX system, while at the same time preserving the existing requirement that a series would not open on a trade if there is no Legal Width Quote. The proposed functionality to provide additional opportunities to open or reopen a series when the market is wider than the specified bid-ask differentials is not novel and the Exchange believes that this proposed rule would allow for more automated Auctions on the Exchange for series that may already be opened on another exchange.¹⁶⁹

Finally, the proposed rule describing how existing and new orders would be processed during a trading halt is designed to provide additional granularity in Exchange rules. Certain of the proposed functionality is based on current processes. The Exchange believes that the proposed differences in order/quote handling would remove impediments to and perfect the mechanism of a free and open market because they align with the proposed

differences in behavior for specified orders and quotes on Pillar. For example, the Exchange believes that repricing resting non-routable orders and quotes during a trading halt to their limit price would be consistent with how such orders would be processed in an Auction if they arrived during a pre-open state. The proposed differences also reflect that on Pillar, ALO Orders would be eligible to participate in an Auction. In addition, the Exchange believes that canceling orders that are subject to the Trading Collar 500 millisecond timer would be consistent with the intent of such functionality, which is to cancel such collared orders after a specified time period.

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 operates in a competitive market and regularly competes with other options exchanges for order flow. The Exchange believes that the transition to Pillar would promote competition among options exchanges by offering a low-latency, deterministic trading platform. The proposed rule changes would support that inter-market competition by allowing the Exchange to offer additional functionality to its OTP Holders and OTP Firms, thereby potentially attracting additional order flow to the Exchange. Otherwise, the proposed changes are not designed to address any competitive issues, but rather to amend the Exchange’s rules relating to options trading to support the transition to Pillar. As discussed in detail above, with this rule filing, the Exchange is not proposing to change its core functionality regarding its price-time priority model, and in particular, how it would rank, display, execute or route orders and quotes. Rather, the Exchange believes that the proposed rule changes would promote consistent use of terminology to support both options and cash equity trading on the Exchange, making the Exchange’s rules easier to navigate. The Exchange does not believe that the proposed rule changes would raise any intra-market competition as the proposed rule changes would be applicable to all OTP Holders and OTP Firms, and reflects the Exchange’s existing price-time priority model, including existing LMM Guarantee, without proposing any substantive changes.

¹⁶⁸ As noted herein, the concept of a Calculated NBBO is consistent with similar concepts utilized on other options exchanges and is therefore not new or novel. *See, e.g.*, Cboe Rule 5.31(a) (regarding used of “Composite Market” concept).

¹⁶⁹ *See, e.g.*, Cboe Rule 5.31.

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. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2021–47, as Modified by Amendment No. 1, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act¹⁷⁰ to determine whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change, as modified by Amendment No. 1.

Pursuant to Section 19(b)(2)(B) of the Act,¹⁷¹ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act¹⁷² which requires, among other things, that the rules of a national securities exchange be "designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, . . . to 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,"¹⁷³ and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.¹⁷⁴

¹⁷⁰ 15 U.S.C. 78s(b)(2)(B).

¹⁷¹ *Id.*

¹⁷² 15 U.S.C. 78f(b)(5).

¹⁷³ *Id.*

¹⁷⁴ *See id.*

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act, any request for an opportunity to make an oral presentation.¹⁷⁵

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved by October 28, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by November 12, 2021. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in Amendment No. 1,¹⁷⁶ and any other issues raised by the proposed rule change under 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–2021–47 on the subject line.

¹⁷⁵ Section 19(b)(2) of the Act grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by an SRO. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

¹⁷⁶ *See supra* note 6.

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–2021–47. 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–2021–47 and should be submitted on or before October 28, 2021. Rebuttal comments should be submitted by November 12, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷⁷

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021–21624 Filed 10–6–21; 8:45 am]

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¹⁷⁷ 17 CFR 200.30–3(a)(12) & 17 CFR 200.30–3(a)(57).



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Part III

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 Parts 2510 and 2590

45 CFR Parts 147 and 149

Requirements Related to Surprise Billing; Part II; Interim Final Rule

**OFFICE OF PERSONNEL
MANAGEMENT****5 CFR Part 890**

RIN 3206-AO29

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD 9955]

RIN 1545-BQ05

DEPARTMENT OF LABOR**Employee Benefits Security
Administration****29 CFR Parts 2510 and 2590**

RIN 1210-AC00

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****45 CFR Parts 147 and 149**

[CMS-9908-IFC]

RIN 0938-AU62

**Requirements Related to Surprise
Billing; Part II**

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 implement provisions of the No Surprises Act that provide for a Federal independent dispute resolution (IDR) (Federal IDR) process to permit group health plans and health insurance issuers offering group or individual health insurance coverage and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain

circumstances. The Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments) are issuing these interim final rules with largely parallel provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage and certified IDR entities, providers, facilities, and providers of air ambulance services. In addition to the interim final rules issued jointly by the Departments, this document also includes interim final rules issued by the Office of Personnel Management (OPM) to clarify how certain No Surprises Act provisions apply to health benefits plans offered by carriers under the Federal Employees Health Benefits (FEHB) Act. In addition to the interim final rules issued jointly by the Departments and OPM, this document includes interim final rules issued by HHS that address good faith estimates of health care items and services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process. The HHS-only interim final rules apply to selected dispute resolution (SDR) entities, providers, facilities, and providers of air ambulance services.

DATES:

Effective date: These regulations are effective on October 7, 2021.

Applicability date: Except as otherwise specified in this paragraph, the regulations issued jointly by the Departments of HHS, Labor, and the Treasury are generally applicable for plan or policy years beginning on or after January 1, 2022. The regulations regarding certification of IDR entities at 26 CFR 54.9816-8T(a) and (e), 29 CFR 2590.716-8(a) and (e), and 45 CFR 149.510(a) and (e) are applicable beginning on October 7, 2021. The OPM-only regulations that apply to health benefits plans are applicable to contract years beginning on or after January 1, 2022. The regulations issued by HHS alone that apply to health care providers, facilities, providers of air ambulance services, and SDR entities are applicable beginning on January 1, 2022, except that the regulations at 45 CFR 149.620(a) and (d) are applicable beginning on October 7, 2021.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 6, 2021.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted

will be shared among the Departments. 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 RIN 1210-AB00. 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 two ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By mail.* You may mail written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-5653, Washington, DC 20210, Attention: RIN 1210-AB00.

You may mail written comments regarding the HHS-only regulations to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention CMS-9908-IFC, P.O. Box 8010, Baltimore, MD 21244-8010. Attention: RIN 0938-AU62.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

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; Elizabeth Schumacher or David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; Deborah Bryant, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301-492-4293.

Customer Service Information: Information from OPM on health benefits plans offered under the 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/agencies/ebsa).

In addition, information from HHS on private health insurance coverage, coverage provided by non-Federal governmental group health plans, and requirements that apply to health care providers, health care facilities, and providers of air ambulance services 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. Preventing Surprise Medical Bills Under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.¹ 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. Surprise billing occurs when an individual receives an unexpected medical bill from a health care provider or facility after receiving 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.

The No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in Subchapter B of chapter 100 of the Internal Revenue

Code (Code), Part 7 of the Employee Retirement Income Security Act (ERISA), and Part D of title XXVII of the Public Health Service Act (PHS Act). Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A-1,² which contain limitations on cost sharing and requirements regarding the timing of initial payments for emergency services furnished by nonparticipating providers and emergency facilities, and for nonemergency services furnished by nonparticipating providers at certain participating health care facilities. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A-1 to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A-2, which contain limitations on cost sharing and requirements for the timing of initial payments for nonparticipating providers of air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process described in Code section 9816, ERISA section 716, and PHS Act section 2799A-1. The No Surprises Act provisions that apply to health care providers and facilities and providers of air ambulance services, such as 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.

On July 13, 2021, the Departments of the Treasury, Labor, and Health and Human Services (Departments) and the Office of Personnel Management (OPM) published interim final rules with request for comments titled, *Requirements Related to Surprise Billing; Part I*, which 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; to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022; and to health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022 (July 2021 interim final rules).³ The July 2021 interim final rules implement Code sections 9816(a)-(b) and 9817(a), ERISA sections 716(a)-(b) and 717(a), and PHS Act sections 2799A-1(a)-(b), 2799A-2(a), 2799A-7, 2799B-1, 2799B-2, 2799B-3, and 2799B-5 to protect consumers from surprise medical bills for emergency services, nonemergency services furnished by nonparticipating providers at participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services. Among other requirements, the July 2021 interim final rules require plans and issuers that provide or cover 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 to cover emergency services without any prior authorization; without regard to whether the health care provider furnishing the emergency services is a participating provider or the services are provided in a participating emergency facility; 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. With respect to emergency services furnished by nonparticipating providers or facilities, nonemergency services furnished by nonparticipating providers at certain participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, the July 2021 interim final rules generally 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.

The July 2021 interim final rules also specify that consumer cost-sharing amounts for emergency services furnished by nonparticipating providers or facilities, and for nonemergency services furnished by nonparticipating providers at certain participating facilities, must be calculated based on one of the following amounts: (1) An amount determined by an applicable All-Payer Model Agreement under

² As discussed later in this preamble, section 102(d)(1) of the No Surprises Act amended the Federal Employees Health Benefits Act, 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 requirements described in section 9816 of the Code, section 716 of ERISA, and section 2799A-1 (as applicable) in the same manner as these provisions apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

³ 86 FR 36872 (July 13, 2021).

¹ Public Law 116-260 (December 27, 2020).

Social Security Act section 1115A; (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, the latter referred to as the qualifying payment amount (QPA). Cost-sharing amounts for air ambulance services provided by nonparticipating providers of air ambulance services must meet the same standards as would apply if the services were provided by a participating provider of air ambulance services and must be calculated using the lesser of the billed charges or the QPA.

Under the July 2021 interim final rules, balance billing for services subject to the requirements in those interim final rules generally is prohibited.⁴ In general, the protections in the July 2021 interim final rules that limit cost sharing and prohibit balance billing do not apply to certain post-stabilization services, or to certain nonemergency services performed by nonparticipating providers at participating health care facilities, if the provider makes certain disclosures to the participant, beneficiary, or enrollee, and obtains the individual's consent to waive balance billing protections. However, this exception to the prohibition on balance billing is narrow. In particular, it is not available in certain circumstances where surprise bills are likely to occur, such as for ancillary services provided by nonparticipating providers in connection with nonemergency care in a participating health care facility. The July 2021 interim final rules also include a number of other specific requirements regarding notice and consent that must be met in order for a provider or facility to be permitted to balance bill a participant, beneficiary, or enrollee for items and services that would otherwise be subject to the prohibition on balance billing.

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. These interim final rules build upon the protections in the July 2021 interim final rules and implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A-1(c) and 2799A-2(b). OPM is also issuing regulations in phases to implement 5 U.S.C. 8902(p).

The Departments and OPM also published a notice of proposed rulemaking on September 16, 2021, titled *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement*.⁵ The proposed rule would, if finalized, implement reporting requirements for air ambulance claims data; 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) of title II of Division BB of the CAA); 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. Later this year, the Departments intend to undertake rulemaking to implement reporting requirements related to pharmacy benefits and prescription drug costs (section 204 of title II of Division BB of the CAA).

The provisions of the No Surprises Act that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in the Code, ERISA, and the PHS Act apply to grandfathered health plans. Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, and the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans.⁶ For example, grandfathered health plans are neither subject to the requirement to cover certain preventive services without cost sharing under PHS Act section 2713 nor to the annual limitation on cost sharing set forth under PHS Act section 2707(b). If a plan or coverage were to relinquish its grandfathered status, it would be required to comply with both provisions, in addition to several other requirements. However, the CAA does not include an exception for grandfathered health plans that is comparable to section 1251 of the Affordable Care Act. Furthermore, section 102(d)(2) of the No Surprises

Act amended section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protections provisions of the No Surprises Act, including those related to choice of health care professional, apply to grandfathered health plans. Therefore, not only do the provisions of these interim final rules and the provisions of the July 2021 interim final rules that apply to group health plans and issuers of group or individual health insurance coverage apply to grandfathered plans, so do the other provisions applicable to group health plans and issuers of group or individual health insurance coverage in titles I and II of Division BB of the CAA.

B. PHS Act Section 2719 and Scope of Claims Eligible for External Review

PHS Act section 2719, as added by the Affordable Care Act, applies to group health plans that are not grandfathered health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets, and sets forth standards for plans and issuers regarding both internal claims and appeals and external review. With respect to external review, PHS Act section 2719 provides for both state external review processes and a Federal external review process that applies in the absence of an applicable state process that meets the requirements of section 2719. Non-grandfathered group health plans that are not self-insured plans (as self-insured plans are not subject to state insurance regulations) and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with an applicable state external review process if that process includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners (the NAIC Uniform Model Act). If a state's external review process does not meet the minimum consumer protection standards set forth in the NAIC Uniform Model Act (or if a plan is self-insured and not subject to state insurance regulation), group health plans and health insurance issuers in the group and individual markets in that state are required to implement an effective external review process that meets minimum standards established by the Departments through rulemaking.

The Departments issued interim final regulations to implement PHS Act section 2719, including the provisions related to external review, in 2010.⁷ An

⁵ 86 FR 51730 (Sept. 16, 2021).

⁶ For a list of the market reform provisions applicable to grandfathered health plans under title XXVII of the PHS Act that the Affordable Care Act added or amended and that were incorporated into ERISA and the Code, visit <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf>.

⁷ 75 FR 43329 (July 23, 2010).

⁴ 45 CFR 149.410(a), 149.420(a) and 149.440(a).

amendment to the interim final rules was issued in 2011.⁸ In 2015, the Departments issued final rules to finalize the interim final regulations.⁹ Among other things, the 2015 final rules address the scope of claims eligible for external review.¹⁰ State external review processes that meet the minimum standards must provide for the external review of adverse benefit determinations that are based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as rescissions. Section 110 of the No Surprises Act directs the Departments, in applying section 2719(b) of the PHS Act, to require the external review process to apply with respect to any adverse determination by a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2.

C. Protecting Uninsured Individuals Through Transparency and Patient-Provider Dispute Resolution

On July 9, 2021, President Biden signed Executive Order 14036, Promoting Competition in the American Economy in order to promote the interests of American workers, businesses, and consumers.¹¹ The executive order acknowledges that robust competition is critical to providing consumers with more choices, better service, and lower prices and directs the Secretary of HHS to support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by the No Surprises Act or any other statutes. Consistent with Executive Order 14036, these interim final rules implement provisions of the No Surprises Act that will provide individuals with more pricing information prior to seeking care, allowing them to shop for the care that is best for them and increase competition in the health care market.

The No Surprises Act also adds a new Part E of title XXVII of the PHS Act establishing requirements applicable to health care providers, providers of air ambulance services, and health care facilities. Section 112 of the No

Surprises Act adds PHS Act sections 2799B–6 and 2799B–7. PHS Act section 2799B–6 requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, an FEHB plan,¹² or a Federal health care program, and, if enrolled in a group health plan, or group or individual health insurance coverage, or a health benefits plan under chapter 89 of title 5,¹³ whether the individual is seeking to have a claim for such item or service submitted to such plan or coverage. In the case that the individual is enrolled in such a plan or coverage (and is seeking to have a claim for such an item or services submitted to such plan or coverage), PHS Act section 2799B–6(2)(A) requires that the provider or facility furnish the good faith estimate to the individual's plan or issuer of such coverage to inform the advanced explanation of benefits that plans and issuers are required to provide a participant, beneficiary, enrollee, or FEHB covered individual under Code section 9816(f), ERISA section 716(f), PHS Act section 2799A–1(f), and 5 U.S.C. 8902(p). In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished who is not enrolled in a plan or coverage, or is not seeking to file a claim with such plan or coverage (self-pay), PHS Act section 2799B–6(2)(B) and these interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the individual.

These interim final rules do not include requirements regarding PHS Act section 2799B–6(2)(A), which require providers and facilities to furnish good faith estimates to plans or issuers.

¹² HHS interprets the requirements described in PHS Act section 2799B–6 to apply with respect to FEHB covered individuals as they would to other individuals enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer. Although PHS Act section 2799B–6 does not reference health benefits plans under chapter 89 of title 5, the definition of “uninsured individual” at PHS Act section 2799B–7 does include individuals who do not have benefits under these health benefits plans, and these sections work together to provide protections for the uninsured (or self-pay) population. Moreover, the requirement for the provision of an advance explanation of benefits required by Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f), as well as 5 U.S.C. 8902(p) cannot be accomplished by a FEHB carrier unless it receives a good faith estimate from a provider in accordance with PHS Act section 2799B–6(2)(A).

¹³ A health benefits plan offered under chapter 89 of title 5, United States Code is also known as an FEHB plan.

Under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) and 5 U.S.C. 8902(p), plans and issuers are required to include the good faith estimates in an advanced explanation of benefits provided to participants, beneficiaries, enrollees, and FEHB covered individuals. As stated in the August 20, 2021, FAQs issued by the Departments, the Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers starting January 1, 2022, the good faith estimates required under PHS Act section 2799B–6, which plans and issuers must then include in the advanced explanation of benefits. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Additionally, stakeholders have requested that the Departments delay the applicability date of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with this section is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement this provision, including establishing appropriate data transfer standards. Until such time, the Departments will defer enforcement of the requirement that plans and issuers must provide an advanced explanation of benefits. HHS will consider whether additional interim solutions for insured consumers are feasible. The Departments note that any rulemaking to fully implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6(2)(A) will include a prospective applicability date that provides plans, issuers, providers, and facilities with a reasonable amount of time to comply with new requirements. HHS encourages states that are primary enforcers of these requirements with regard to providers and issuers to take a similar enforcement approach, and

⁸ 76 FR 37207 (June 10, 2011).

⁹ 80 FR 72191 (Nov. 18, 2015).

¹⁰ 26 CFR 54.9815–2719(d)(1); 29 CFR 2590.715–2719(d)(1); 45 CFR 147.136(d)(1).

¹¹ 86 FR 36987 (Jul 9, 2021).

will not determine that a state is failing to substantially enforce these requirements if it takes such an approach.

Nonetheless, providers and facilities will be subject to enforcement action for failure to provide a good faith estimate to individuals not enrolled in a plan or coverage, or not seeking to have a claim for such item or services submitted to such plan or issuer of such coverage, as specified under these interim final rules. HHS seeks comment on this approach.

On November 12, 2020, the Departments issued the Transparency in Coverage final rules,¹⁴ which require group health plans and health insurance issuers of group or individual health insurance coverage to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request. This information must be available for plan years—or in the individual market, for policy years—beginning on or after January 1, 2023 with respect to 500 specified items and services, and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024. The Departments are of the view that the disclosure requirements to participants, beneficiaries, and enrollees under the Transparency in Coverage final rules, and those required under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f), are substantially similar and therefore the Departments seek comment on whether there are ways to leverage the Transparency in Coverage requirements, including whether there are ways for plans and issuers to provide the information required in the Transparency in Coverage final rules to participants, beneficiaries, and enrollees during plan or policy years beginning in 2022. The Departments also seek comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request for 2022.

Section 112 of the No Surprises Act also adds PHS Act section 2799B–7, which directs the Secretary of HHS to establish a process under which uninsured (or self-pay) individuals can avail themselves of a patient-provider dispute resolution process if their billed charges after receiving an item or service are substantially in excess of the expected charges listed in the good faith estimate furnished by the provider or

facility, pursuant to PHS Act section 2799B–6. Under PHS Act section 2799B–7, an uninsured (or self-pay) individual means, with respect to an item or service, an individual who does not have benefits for such item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code (or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but does not seek to have a claim for such item or service submitted to such plan or coverage).

II. Executive Summary

A. Departments of the Treasury, Labor, and HHS: Federal IDR Process and External Review

In order to implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A–1(c) and 2799A–2(b), as added by sections 103 and 105 of the No Surprises Act, these interim final rules establish a Federal IDR process that nonparticipating providers or facilities, nonparticipating providers of air ambulance services, and group health plans and health insurance issuers in the group and individual market may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services. More specifically, the Federal IDR provisions may be used to determine the out-of-network rate for certain emergency services, nonemergency items and services furnished by nonparticipating providers at participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services where an All-Payer Model Agreement or specified state law does not apply.

Under Code sections 9816(c)(1)(A) and 9817(b)(1)(A), ERISA sections 716(c)(1)(A) and 717(b)(1)(A), PHS Act sections 2799A–1(c)(1)(A) and 2799A–2(b)(1)(A), and these interim final rules, upon receiving an initial payment or notice of denial of payment from a plan or issuer with respect to such items or services, such provider or facility or provider of air ambulance services (as applicable) or plan or issuer (as applicable) may initiate an open negotiation period within 30 business days beginning on the date the provider

or facility receives the initial payment or notice of denial of payment. The open negotiation period may continue for up to 30 business days beginning on the date that either party first initiates the open negotiation period. The parties may discontinue the negotiation if they agree on an out-of-network rate before the last day of the 30-business-day open negotiation period. If the parties cannot agree on an out-of-network rate, they must exhaust the 30-business-day open negotiation period before initiating the Federal IDR process. Either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The parties may select a certified IDR entity, or if the parties do not select a certified IDR entity, the Departments will do so. The No Surprises Act and these interim final rules specify that the certified IDR entity selected cannot be a party to the determination or an employee or agent of such a party, or have a material familial, financial, or professional relationship with such party.

In resolving the disputes through the Federal IDR process, the No Surprises Act and these interim final rules provide that each party must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service in dispute and other information related to the offer as requested by the certified IDR entity within 10 business days of selection of the certified IDR entity and may submit additional information for the certified IDR entity to consider. In making a determination of which payment offer to select, these interim final rules specify that the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. These interim final rules further provide that the certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that credible information submitted by either party clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on the additional factors set forth in Code sections 9816(c)(5)(C)(ii) and 9817(b)(5)(C)(ii), ERISA sections 716(c)(5)(C)(ii) and 717(b)(5)(C)(ii), and PHS Act sections 2799A–1(c)(5)(C)(ii) and 2799A–2(b)(5)(C)(ii). The certified IDR entity may not consider usual and customary charges, the amount that would have been billed (including billed charges that are directed to the plan or issuer) if the protections of 45 CFR 149.410,

¹⁴ 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b).

149.420, or 149.440¹⁵ (as applicable) had not applied, or any public payor payment or reimbursement rates.¹⁶ As discussed more fully in section III.D.4.ii. of this preamble, this approach is consistent with the No Surprises Act's emphasis on the QPA, both as the basis of the surprise billing protections also included in the statute and implemented by the July 2021 interim final rules and as the sole factor identified without any qualification by the statute.¹⁷ The Departments are of the view that implementing the Federal IDR process in this manner encourages predictable outcomes, which will reduce the use of the Federal IDR process over time and the associated administrative fees born by the parties, while providing equitable and clear standards for when payment amounts may deviate from the QPA, as appropriate.

The No Surprises Act and these interim final rules also set forth requirements for certification of IDR entities by the Departments. To become certified IDR entities, IDR entities must provide written documentation demonstrating that they meet the eligibility criteria, including having sufficient expertise and staffing to conduct determinations on a timely basis, being free of conflicts of interest, being accredited by a nationally recognized and relevant accrediting body (such as URAC) or otherwise ensuring that IDR entity personnel possess the requisite training to conduct payment determinations (for example,

providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association (AAA), the American Health Law Association (AHLA), or a similar organization), ensuring policies and procedures are in place to maintain confidentiality of individually identifiable health information, providing a fixed fee for single determinations and a separate fee for batched determinations, having a procedure in place to retain certified IDR entity fees and retain and remit administrative fees, meeting appropriate indicators of fiscal integrity and stability, evidencing its ability to collect and transmit the information required to be reported to the Departments, and properly carrying out the requirements of the Federal IDR process in accordance with the law. These interim final rules also establish a process whereby members of the public, providers, facilities, providers of air ambulance services, plans, or issuers may petition for the denial or revocation of certification of an IDR entity. Finally, these interim final rules require the collection of information related to the Federal IDR process from certified IDR entities in order to allow the Departments to quarterly publish information on IDR payment determinations.

The Departments are also establishing a Federal IDR portal to administer the Federal IDR process. The Departments' Federal IDR portal will be available at <https://www.nsa-idr.cms.gov> and will be used throughout the Federal IDR process to maximize efficiency and reduce burden. As discussed throughout this preamble, the Federal IDR portal may be used to satisfy various requirements under these interim final rules, including provision of notices, Federal IDR initiation, submission of an application to be a certified IDR entity, as well as satisfying reporting requirements.

These interim final rules also amend final regulations issued by the Departments in 2015 related to external review in order to implement section 110 of the No Surprises Act. Section 110 requires that “[i]n applying the provisions of section 2719(b) of the [PHS Act] to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of [HHS], Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a

plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2, including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.” Accordingly, these interim final rules amend the final regulations regarding external review in two ways. First, the scope of adverse benefit determinations eligible for external review is amended to ensure that issues related to compliance with the specified provisions of the No Surprises Act fall within that scope. Several examples are also added to provide greater clarity to stakeholders regarding the expanded scope. Second, applicability provisions are amended to require that grandfathered health plans, which generally are exempt from requirements related to external review, must nonetheless provide for external review of adverse benefit determinations for claims subject to the cost-sharing and surprise billing protections in the No Surprises Act. The Departments seek comment on all aspects of these interim final rules.

B. Office of Personnel Management: Federal IDR Process for FEHB Carriers

The OPM interim final rules amend existing 5 CFR 890.114(a) to include references to the Treasury, DOL, and HHS interim final rules to clarify that pursuant to 5 U.S.C. 8902(p), FEHB carriers are also subject to the Federal IDR process set forth in those regulations with respect to an item or service eligible for determination through open negotiation or the Federal IDR process furnished by a FEHB carrier offering a health benefits plan in the same manner as those 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 FEHB carrier's contract. Through new 5 CFR 890.114(d), OPM adopts the Departments' interim final rules as conformed by terms unique to the FEHB Program. In 5 CFR 890.114(d), OPM adopts the Departments' rules as necessary to properly integrate with existing FEHB Program structure and sets forth circumstances in which OPM will enforce these rules as applied to FEHB carriers. The OPM interim final rules require FEHB carrier notice to the OPM Director (herein, the Director) of an FEHB carrier's notice of initiation, or receipt of a provider's notice of initiation, of the Federal IDR process. The Director will coordinate with the Departments in matters regarding FEHB

¹⁵ The July 2021 interim final rules prohibit nonparticipating emergency facilities and nonparticipating providers furnishing emergency services from billing participants, beneficiaries, or enrollees for payment amounts that exceed the cost-sharing requirement for those items or services. The July 2021 interim final rules also generally prohibit nonparticipating providers furnishing nonemergency items and services at participating facilities from balance billing participants, beneficiaries, or enrollees for those items or services. In addition, the July 2021 interim final rules prohibit nonparticipating providers of air ambulance services furnishing air ambulance services for which benefits are available under a group health plan or group or individual health insurance coverage from balance billing participants, beneficiaries, or enrollees for those items or services.

¹⁶ Public payor payment and reimbursement rates include reimbursement rates under the Medicare program under title XVIII of the Social Security Act, under the Medicaid program under title XIX of such Act, under the Children's Health Insurance Program under title XXI of such Act, under the TRICARE program under chapter 55 of title 10, United States Code, and under chapter 17 of title 38, United States Code.

¹⁷ The No Surprises Act limits the certified IDR entity's consideration of additional factors by prohibiting the certified IDR entity from considering certain other factors, such as usual and customary charges and billed charges, in making a payment determination.

carriers requiring resolution under the Federal IDR process and with respect to oversight of certified IDR entities' reports regarding FEHB carriers. As discussed in the July 2021 interim final rules, all out-of-network rate determinations regarding IDR items or services eligible for determination through open negotiation or the Federal IDR process under the No Surprises Act with respect to FEHB plans or carriers that are not resolved by open negotiation are subject to the Federal IDR process unless OPM contracts with FEHB carriers include terms that adopt state law as governing for this purpose.

C. Department of HHS: Protections for the Uninsured

To ensure that uninsured (or self-pay) individuals are also afforded protections against surprise health care costs, the No Surprises Act includes provisions that require providers and facilities to furnish good faith estimates to uninsured (or self-pay) individuals upon their request and at the time of scheduling the item or service. In order to implement these provisions under PHS Act sections 2799B-6(1) and 2799B-6(2)(B), HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and requirements for providing a good faith estimate to uninsured (or self-pay) individuals. These interim final rules define uninsured (or self-pay) individuals to include those who do not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, a Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code, or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but who does not seek to have a claim for such item or service submitted to such plan or coverage. PHS Act section 2799B-6, added by section 112 of the No Surprises Act, does not specifically define a Federal health care program and also does not reference health benefits plans under chapter 89 of title 5. However, PHS Act section 2799B-7, which was also added by section 112 of the No Surprises Act, and which provides protections related to the good faith estimate required under PHS Act section 2799B-6, defines an uninsured individual to include individuals not enrolled in a Federal health care program (as defined in

section 1128B(f) of the Social Security Act) and individuals not enrolled in health benefits plans under chapter 89 of title 5. To align these two related sections, HHS is adopting the definition of an uninsured (or self-pay) individual at PHS Act section 2799B-7 for the purposes of the interim final rules at 45 CFR 149.610 which implements PHS Act section 2799B-6(1) and 2799B-6(2)(B) and 45 CFR 149.620 which implements PHS Act section 2799B-7.

The definition of uninsured (or self-pay) individuals in these interim final rules includes individuals enrolled in individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, but not seeking to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals, therefore these interim final rules include the term self-pay when discussing uninsured individuals.

Under PHS Act section 2791(b)(5), short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage. Therefore, for purposes of 45 CFR 149.610 and 45 CFR 149.620, uninsured (or self-pay) individuals include individuals who are enrolled in short-term, limited-duration insurance and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code. Thus, providers and facilities will be required to provide to such individuals a good faith estimate and such individuals will be able to avail themselves of the patient-provider dispute resolution process, where applicable.

PHS Act section 2799B-6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing the items or services listed on the good faith estimate (including any items or services that are reasonably expected to be provided in conjunction with such scheduled or requested items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes for any such items or services.

As discussed in section I.C. of this preamble, requirements to implement PHS Act section 2799B-6(2)(A) are not

included in these interim final rules given the challenges of developing the technical infrastructure necessary to transmit such data from providers and facilities to plans and issuers. The requirements in these interim final rules apply only to good faith estimate notifications for uninsured (or self-pay) individuals as described in PHS Act section 2799B-6(2)(B) and in these interim final rules. HHS acknowledges that PHS Act section 2799B-6 also requires providers and facilities to make certain disclosures to an individual's plan or coverage if the individual is enrolled in such a plan or coverage and is seeking to have a claim for such items or services submitted to such plan or coverage. Specifically, section 2799B-6(2)(A) requires a provider or facility to provide such a plan or issuer notification of the good faith estimate of expected charges for furnishing an item or service on the same terms as provided to individuals.

Health care providers and health care facilities are required under PHS Act section 2799B-6 to furnish a notification of the good faith estimate of expected charges to an uninsured (or self-pay) individual who schedules an item or service, and to an individual who has not yet scheduled an item or service, but requests a good faith estimate. PHS Act section 2799B-6 requires providers and facilities to furnish a good faith estimate to an uninsured (or self-pay) individual who schedules an item or service at least 3 business days before the date such item or service is to be so furnished, not later than 1 business day after the date of such scheduling (or, in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the uninsured (or self-pay) individual), not later than 3 business days after the date of such scheduling or such request). As further discussed in section VI of this preamble, in instances where an uninsured (or self-pay) individual requests a good faith estimate of expected charges, but the item or service has not been scheduled, these interim final rules require that the treating provider furnish a good faith estimate to the uninsured (or self-pay) individual, within 3 business days of such request. For example, if an uninsured (or self-pay) individual schedules an item or service on Monday, January 3 to be provided on Thursday, January 6, the provider and facility must furnish a good faith estimate no later than Tuesday, January 4. If scheduling occurs on Monday, January 3 for items or services to be

provided on Thursday, January 13, the provider and facility must furnish a good faith estimate no later than Thursday, January 6. If an uninsured (or self-pay) individual requests a good faith estimate on Monday, January 3 for items or services not yet scheduled, the provider and facility must furnish the good faith estimate no later than Thursday, January 6.

These interim final rules include definitions relating to good faith estimates of expected charges for uninsured (or self-pay) individuals for scheduled items or services and upon request. These interim final rules also include requirements for providers and facilities regarding the contents of the good faith estimates and the manner in which good faith estimates must be provided.

PHS Act section 2799B–7 provides further protections for the uninsured (or self-pay) individual by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received from a provider or facility a good faith estimate of the expected charges, and who, after being furnished the item or service, is billed an amount that is substantially in excess of the expected charges in the good faith estimate, may seek a determination from a certified dispute resolution entity of the amount to be paid to the provider or facility.

HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process, including specific definitions related to the process. HHS is also codifying provisions related to eligibility for the patient-provider dispute resolution process, and selection of an SDR entity. HHS clarifies that while SDR entities provide a similar function and must meet similar requirements as certified IDR entities, SDR entities are specific to the patient-provider dispute resolution process. These interim final rules also codify requirements related to the determination of payment amounts by SDR entities, fees associated with the patient-provider dispute resolution process, certification of SDR entities, and deferral to state-established patient-provider dispute resolution processes that meet certain minimum Federal standards.

III. Overview of the Interim Final Rules Regarding the Federal Independent Dispute Resolution Process for Plans, Issuers, Providers, Facilities, and Providers of Air Ambulance Services—Departments of the Treasury, Labor, and HHS

A. Definitions

Code section 9816, ERISA section 716, and PHS Act sections 2799A–1 and 2799A–2 include defined terms that are specific to the law's requirements and implementation.¹⁸ The definitions in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 apply to these interim final rules; these interim final rules also define additional terms specific to the Federal IDR process. Under these interim final rules, “batched items and services” means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. For a qualified IDR item or service to be included as a batched item or service, the qualified IDR item or service must satisfy the criteria for batching set forth in 26 CFR 54.9816–8T(c)(3), 29 CFR 2590.716–8(c)(3), and 45 CFR 149.510(c)(3). “Certified IDR entity” means an entity responsible for conducting determinations under 26 CFR 54.9816–8T(c), 29 CFR 2590.716–8(c), and 45 CFR 149.510(c) that meets the certification criteria specified in 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e) and that has been certified by the Departments. Separately, “IDR entity” means an entity that may apply or has applied for certification to conduct determinations under 26 CFR 54.9816–8T(c), 29 CFR 2590.716–8(c), and 45 CFR 149.510(c) and currently is not certified by the Departments pursuant to 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e). If a certified IDR entity's certification has expired or has been revoked as a result of the process described in 26 CFR 54.9816–8T(e)(6), 29 CFR 2590.716–8(e)(6), and 45 CFR 149.510(e)(6), upon the date of the expiration or revocation, the formerly-

¹⁸ To implement these interim final rules regarding the Federal IDR process under the PHS Act, HHS is amending 45 part CFR 149 by adding new Subparts F and G. Additionally, the Departments are amending 26 CFR 54.9816–1T and 54.9816–2T, 29 CFR 2590.716–1 and 2590.716–2 and 45 CFR 149.10 and 149.20 to expand the scope and applicability of this part to include IDR entities and the Federal IDR process. HHS is also amending 45 CFR 149.10 and 149.20 to expand the scope and applicability of this part to include SDR entities, the good faith estimate requirements, and patient-provider dispute resolution process.

certified IDR entity will be referred to as an IDR entity.

These interim final rules also define certain terms related to conflict-of-interest standards applicable to certified IDR entities. Stakeholders have emphasized the importance of ensuring a broad conflict-of-interest standard in order to avoid the risk of biased IDR payment determinations (or the appearance of biased IDR payment determinations). In general, a “conflict of interest” means, with respect to a party to a payment determination, a certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of a certified IDR entity to make an unbiased and impartial payment determination. For purposes of these interim final rules, a conflict of interest exists when a certified IDR entity is a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility,¹⁹ or a provider of air ambulance services. While the statute does not specify that the IDR entity must not be a health insurance issuer offering short-term, limited-duration insurance, the Departments have determined that such entities should not be eligible for certification, due to their similarity to health insurance issuers offering group and individual health insurance coverage and their inherent interest as issuers in keeping reimbursement rates for providers, facilities, and providers of air ambulance services low. A conflict of interest also exists when a certified IDR entity is an affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or provider, facility, or provider of air ambulance services. A conflict of interest also exists when a certified IDR

¹⁹ Similar to the July 2021 interim final rules, the term “facility” indicates a facility that furnishes health care services that is subject to the surprise billing protections of the No Surprises Act, such as a hospital (including a hospital's emergency department), urgent care center, or ambulatory surgical center. For purposes of good faith estimates under 45 CFR 149.610 and the Patient-Provider dispute resolution process in 45 CFR 149.620 “facility” includes an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any state in which state or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such state or locality responsible for licensing such institution as meeting the standards established for such licensing.

entity is an affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; FEHB carriers; or providers, facilities, or providers of air ambulance services. Additionally, a conflict of interest exists when a certified IDR entity has, or any personnel assigned to a determination have a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier's employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute. The Departments are of the view that an officer, director, or management employee of the plan issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute are individuals who could have significant involvement with the dispute. Relationships with these individuals could therefore improperly affect the certified IDR entities' ability to be impartial.

These interim final rules also define what constitutes a material familial relationship, a material financial relationship, or material professional relationship with a party to the payment determination. In developing these definitions, the Departments looked to states' conflict-of-interest standards for external review and arbitrations of surprise billing claims. These state standards typically use terms that are similar to those used in Code section 9816(c)(4)(F)(i)(II), ERISA section 716(c)(4)(F)(i)(II), and PHS Act section 2799A-1(c)(4)(F)(i)(II).²⁰ By adopting definitions that largely mirror these state standards, the Departments seek to ensure that the definitions are workable and increase the likelihood that IDR entities may be familiar with these

standards, if they have performed services in these states. Accordingly, these interim final rules provide that the term "material familial relationship" means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner. "Material financial relationship" means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any payment determination under the Federal IDR process. Under the definition of "material financial relationship," annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation. Finally, with respect to terms related to the conflict-of-interest standards, "material professional relationship" means any physician-patient relationship, any partnership or employment relationship or affiliation, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity, or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity. The Departments solicit comment on whether the defined terms related to the conflict-of-interest standards should include threshold requirements to further define the level of relationship that would rise to the level of a conflict of interest.

Additionally, under these interim final rules, the Departments define certain terms related to confidentiality, information security, and privacy requirements that apply to an IDR entity seeking certification under these interim final rules. Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A-1(c)(4)(A)(v) require certified IDR entities to maintain the confidentiality of individually identifiable health information (IIHI) obtained while making payment determinations and engaging in other activities related to the Federal IDR process. In establishing definitions for these terms, the Departments looked to

existing Federal standards, particularly the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the privacy, security, and breach notification standards under 45 CFR part 160 A and subparts A, C, D, and E of part 164, because the Departments are of the view that these provisions are industry standards. The Departments have modified these standards in some cases to fit the circumstances of IDR entities.

These interim final rules define "Individually identifiable health information (IIHI)" to mean any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.²¹ Finally, these interim final rules define "Unsecured IIHI" to mean IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Departments. For technologies and methodologies approved for this purpose, certified IDR entities should refer to the HHS Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals.²²

These interim final rules provide that the term "breach" means the acquisition, access, use, or disclosure of IIHI in a manner not permitted under 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) that compromises the security or privacy of the IIHI. Under these interim final rules, a breach excludes any unintentional acquisition, access, or use of IIHI by personnel, including a contractor or subcontractor, acting under the authority of a certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a

²¹ Note that this definition is broader than the definition of IIHI set forth in the Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR 160.103.

²² HHS Office for Civil Rights, "Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals," available at <https://www.hhs.gov/guidance/document/guidance-render-unsecured-protected-health-information-unusable-unreadable-or>.

²⁰ See e.g., WAC 284-43A-010; N.Y. Comp. Codes R. & Regs. tit. 11 section 410.2.

manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). Also excluded is any inadvertent disclosure by a person who is authorized to access IIHI as personnel of a certified IDR entity to another person authorized to access IIHI as personnel of the same certified IDR entity (including a contractor or subcontractor of the certified IDR entity), and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). Finally, also excluded is a disclosure of IIHI when a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information. For example, if, while conducting an IDR payment determination, a certified IDR entity sends paperwork containing IIHI to the wrong address and the paperwork is returned by the post office, unopened, as undeliverable, the certified IDR entity can conclude that the entity at the improper address could not reasonably have retained the information. The definition of breach additionally provides that an acquisition, access, use, or disclosure of IIHI in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment of at least the following factors: (1) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; (2) the unauthorized person who used the IIHI or to whom the disclosure was made; (3) whether the IIHI was actually acquired or viewed; and (4) the extent to which the risk to the IIHI has been mitigated.

Additionally, “qualified IDR item or service” means an item or service that is either an emergency service furnished by a nonparticipating provider or nonparticipating emergency facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or 45 CFR 149.110, for which the conditions of 45 CFR 149.410(b) (regarding receipt of notice of surprise billing protections and providing consent to waive them) are not met. The term also means an item or service furnished by a nonparticipating provider at a participating health care facility subject

to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.716–5, and 45 CFR 149.120, for which the conditions of 149.420(c)–(i) (regarding receipt of notice of surprise billing protections and providing consent to waive them) are not met, for which the provider or facility (as applicable) or plan or issuer submits a valid Notice of IDR Initiation initiating the Federal IDR process. For the Notice of IDR Initiation to be valid, the open negotiation period under 26 CFR 54.9816–8T(b)(1), 29 CFR 2590.716–8(b)(1), and 45 CFR 149.510(b)(1) must have lapsed, and an agreement on the payment amount must not have been reached. The term qualified IDR item or service includes air ambulance services provided by nonparticipating providers of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, and 45 CFR 149.130, as these services are defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30, for which the open negotiation period under 26 CFR 54.9816–8T(b)(1), 29 CFR 2590.716–8(b)(1), and 45 CFR 149.510(b)(1) has lapsed, and no agreement on the payment amount has been reached.

The term “qualified IDR item or service” does not include items and services for which the out-of-network rate is determined by an All-Payer Model Agreement under section 1115A of the Social Security Act, or by reference to a specified state law. Additionally, this term does not include items or services submitted by the initiating party that are subject to the 90-calendar-day suspension period under 26 CFR 54.9816–8T(c)(4)(vii)(B), 29 CFR 2590.716–8(c)(4)(vii)(B), and 45 CFR 149.510(c)(4)(vii)(B). However, the term may include items or services that are subject to the 90-calendar-day suspension period if they are submitted during the subsequent 30-business-day period, as allowed under these interim final rules. The Departments solicit comment on these definitions, including whether other terms should be defined.

B. The Term “Days”

The No Surprises Act specifies a number of time periods that providers, facilities, providers of air ambulance services, plans, issuers, certified IDR entities, and the Departments must abide by throughout the course of the Federal IDR process, including time periods for initiation of the Federal IDR process, selection of a certified IDR entity, submission of documents, and payment determinations. The statute is largely silent on whether the term “days” used in these provisions means business days or calendar days.

However, in certain provisions, the No Surprises Act specifies the use of calendar days or business days, indicating that where the statute is silent the Departments may choose either meaning. The Departments received feedback from stakeholders that meeting various deadlines under the Federal IDR process may be challenging (for example, depending on a certified IDR entity’s case load or the number of claims that a provider or facility batches together) and that, if possible, additional time should be provided for the parties and the certified IDR entity to meet these deadlines. The Departments are of the view that in order to provide parties with the most time permitted under the statute to meet the various deadlines under the Federal IDR process as set forth in the No Surprises Act, business days should be used, unless there is a reason to use calendar days. For example, these interim final rules provide that calendar days are used for the timing requirement for the non-prevailing party to make payment after the certified IDR entity issues a written determination, as well as the requirement barring the initiation of the Federal IDR process for a payment dispute that concerns the same or similar qualified IDR item or service that was the subject of the initial notification during the 90-calendar-day period following the initial determination discussed later in this preamble. In these instances, the Departments are of the view that once a decision has been rendered, these interim final rules should not unduly delay the payment entitled under that decision. Moreover, in terms of the 90-day suspension period, the Departments are of the view that using a business day standard here has the potential to create an unnecessary barrier to accessing the Federal IDR process.

Furthermore, the Departments are of the view that using business days will avoid issues that may arise if deadlines were to fall on weekends or Federal holidays. Therefore, business days (Monday through Friday, not including Federal holidays) instead of calendar days are used throughout these interim final rules for the Federal IDR process unless otherwise indicated, regardless of whether a nonparticipating provider or facility, or a plan or issuer’s business typically operates on weekend days.

C. Open Negotiation and Initiation of the Federal IDR Process

Code section 9816(c)(1)(A), ERISA section 716(c)(1)(A), PHS Act section 2799A–1(c)(1)(A), and these interim final rules provide that with respect to an emergency service, a nonemergency

item or service furnished by a nonparticipating provider at a participating facility subject to the surprise billing protections for which the notice and consent exceptions do not apply, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified state law as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30, the provider or facility, or plan or issuer, may engage in open negotiations to determine the total out-of-network rate (including any cost sharing). If the parties fail to reach an agreement through open negotiation, they may initiate the Federal IDR process. Code section 9817(b), ERISA section 717(b), and PHS Act section 2799A-2(b) provide that out-of-network rates for air ambulance services may be determined through open negotiation or an IDR process that is largely identical to the process provided for in Code section 9816(c), ERISA section 716(c), and PHS Act section 2799A-1(c), provided the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified state law as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30. Therefore, where applicable, providers of air ambulance services are included in the preamble and regulatory language text describing open negotiations and the Federal IDR process. The primary distinctions between air ambulance services and other health care services apply in how the certified IDR entity should select an offer and in the obligations on the certified IDR entity regarding reporting of information relating to the Federal IDR process.

1. Open Negotiation

The open negotiation period may be initiated by any party during the 30-business-day period beginning on the day the nonparticipating provider, facility, or nonparticipating provider of air ambulance services receives either an initial payment or a notice of denial of payment for an item or service.²³ If the provider, facility, or provider of air ambulance services accepts such initial payment as the total payment, that initial payment combined with the cost-sharing amount for the item or service is the out-of-network rate, as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-

3, and 45 CFR 149.30. Under the July 2021 interim final rules, the plan or issuer must provide in writing, with each initial payment or notice of denial of payment, certain information, including a statement that if the provider, facility, or provider of air ambulance services, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the out-of-network rate, the provider, facility, or provider of air ambulance services may contact the appropriate person or office to initiate open negotiation, and that if the 30-business-day open negotiation period does not result in an agreement on the out-of-network rate, generally, the provider, facility, or provider of air ambulance services may initiate the Federal IDR process. The plan or issuer must also provide 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 the item or service.

In order for a plan, issuer, provider, facility, or provider of air ambulance services to know when it is a party to an open negotiation period and which items or services are subject to negotiation, these interim final rules require that the party initiating the open negotiation must provide written notice to the other party of its intent to negotiate, referred to as an open negotiation notice. The open negotiation notice must include information sufficient to identify the items or services subject to negotiation, including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and contact information of the party sending the open negotiation notice. The open negotiation notice must be sent within 30 business days of the initial payment or notice of denial of payment from the plan or issuer regarding such item or service and must be provided in writing. The party sending the open negotiation notice may satisfy this requirement by providing the notice to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and (2) the notice is provided in paper form free of charge upon request. For example, if a provider sends an open negotiation notice to the email address identified by the group health plan or issuer in the

notice of denial or initial payment, such electronic delivery would satisfy this requirement (as long as the provider also sends the notice in paper form free of charge upon request). Similarly, if a provider, facility, or provider of air ambulance services submits a claim electronically, this could provide the plan or issuer with a good faith belief that the electronic method is readily accessible to the other party.

The 30-business-day open negotiation period begins on the day on which the open negotiation notice is first sent by a party. The Departments expect that most open negotiation notices will be sent electronically, and that, in general, the date the notice is sent will also be the date the notice is received. Furthermore, given that the parties have already made initial contact (namely that the provider or facility has transmitted a bill to the plan or issuer, and the plan or issuer has sent a notice of denial or initial payment to the provider or facility), the Departments anticipate that the parties should be able to provide effective notice without problems, and encourage the parties to take reasonable measures to ensure that actual notice is provided, such as confirming that the email address is accurate. The Departments caution that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of these interim final rules. Therefore, the Departments encourage parties submitting open negotiation notices to take steps to confirm the other party's contact information and confirm receipt by the other party, through approaches such as read receipts, especially where a party does not initially respond to an open negotiation notice. The Departments solicit comment on whether there are any challenges or additional clarifications needed to ensure the parties are afforded the full open negotiation period, including whether there are any challenges regarding designating the date the notice is sent as the commencement date of the open negotiation period.

To facilitate communication between parties and compliance with this notice requirement, the Departments are concurrently issuing a standard notice

²³ As clarified in the July 2021 interim final rules, the 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, prior to the beginning of any open negotiations or initiation of the Federal IDR process.

that the parties must use to satisfy the open negotiation notice requirement.

Negotiation during the open negotiation period will occur without the involvement of the Departments or a certified IDR entity. The Departments note that this requirement for a 30-business-day open negotiation period prior to initiating the Federal IDR process does not preclude the parties from reaching an agreement in fewer than 30 business days. However, in the event the parties do not reach an agreement, the parties must still exhaust the 30-business-day open negotiation period before either party may initiate the Federal IDR process. The Departments encourage parties to negotiate in good faith during this time period to reach an agreement on the out-of-network rate. To the extent parties reach agreement during this period, they can avoid the administrative costs associated with the Federal IDR process.

2. Initiating the Federal IDR Process and the Notice of IDR Initiation

Code section 9816(c)(1)(B), ERISA section 716(c)(1)(B), PHS Act section 2799A-1(c)(1)(B), and these interim final rules provide that with respect to items or services that were subject to open negotiation, if the parties have not reached an agreed-upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. A party may not initiate the Federal IDR process if, with respect to an item or service, the party knows or reasonably should have known that the provider or facility provided notice and obtained consent from a participant, beneficiary, or enrollee to waive surprise billing protections consistent with PHS Act sections 2799B-1(a) and 2799B-2(a) and the implementing regulations at 45 CFR 149.410(b) and 149.420(c)-(i).

To initiate the Federal IDR process, the initiating party must submit a notice to the other party and to the Departments (Notice of IDR Initiation) through the Federal IDR portal. The Notice of IDR Initiation must include: (1) Information sufficient to identify the qualified IDR items or services (and whether the qualified IDR items or services are designated as batched items and services), including the dates and location of the items or services, the type of qualified IDR items or services (such as emergency services, post-stabilization services, professional services, hospital-based services), corresponding service and place-of-service codes, the amount of cost

sharing allowed and the amount of the initial payment made by the plan or issuer for the qualified IDR items or services, if applicable; (2) the names and contact information of the parties involved, including email addresses, phone numbers, and mailing addresses; (3) the state where the qualified IDR items or services were furnished; (4) the commencement date of the open negotiation period; (5) the initiating party's preferred certified IDR entity; (6) an attestation that the items or services are qualified IDR items and services within the scope of the Federal IDR process; (7) the QPA; (8) information about the QPA as described in 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d); and (9) general information describing the Federal IDR process. This general information will help ensure that the non-initiating party is informed about the process and is familiar with the next steps. Such general information should include a description of the scope of the Federal IDR process and key deadlines in the Federal IDR process, including the dates to initiate the Federal IDR process, how to select a certified IDR entity, and the process for selecting an offer. The Departments have developed a form that parties must use to satisfy this requirement to provide general information describing the Federal IDR process.

As with the open negotiation notice, the initiating party may provide the Notice of IDR Initiation to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and (2) the notice is provided in paper form free of charge upon request.

In addition to furnishing notice to the non-initiating party, the initiating party must also furnish the Notice of IDR Initiation to the Departments on the same day the notice is furnished to the non-initiating party. The initiating party must provide its Notice of IDR Initiation through the Departments' Federal IDR portal. Moreover, IDR entities, certified IDR entities and disputing parties will be required to use the Federal IDR portal to perform certain functions related to the Federal IDR process. The Federal IDR portal will be used to facilitate and support IDR entity certification, the initiation of the Federal IDR process, the selection of certified IDR entities, the submission of supporting documentation to certified IDR entities, and the submission of certified IDR entity reporting metrics, as required by these interim final rules.

Under Code section 9816(c)(1)(B), ERISA section 716(c)(1)(B), and PHS Act section 2799A-1(c)(1)(B), the date of initiation of the Federal IDR process will be the date of the submission or such other date specified by the Departments that is not later than the date of receipt of the Notice of IDR Initiation by both the other party and the Departments. Consistent with the flexibility provided by the statute to specify an alternate date of initiation, these interim final rules specify that the initiation date of the Federal IDR process is the date of receipt of the Notice of IDR Initiation by the Departments. As noted, since the Departments will monitor the Federal IDR portal, submitting the Notice of IDR Initiation through the Federal IDR portal will provide a clear date on which the Notice of IDR Initiation has been received by the Departments. This approach will better enable the Departments to meet the statutory requirement to select a certified IDR entity within 6 business days of the initiation of the IDR process in instances in which the parties have not jointly selected a certified IDR entity. The Departments will acknowledge and confirm the initiation date with both parties upon receipt of the Notice of IDR Initiation. Given that the Departments expect most of these notices to be provided electronically, and that the parties will have been in continuous contact by this point in the process (through the submission of the initial bill, the remittance of the initial payment of the claim or notice of denial of payment, the submission of the open negotiation notice, and negotiations during the open negotiation period), the Departments expect minimal delay between when the Departments are notified through the portal and when the opposing party is notified (either by the initiating party or the Departments). The Departments solicit comment on both the content of the Notice of IDR Initiation as well as the manner for providing the notices as set forth under these interim final rules.

D. Federal IDR Process Following Initiation

1. Selection of Certified IDR Entity

Under Code section 9816(c)(4)(F), ERISA section 716(c)(4)(F), and PHS Act section 2799A-1(c)(4)(F), the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable) that are parties to the Federal IDR process may jointly select a certified IDR entity no later than 3 business days

following the date of the IDR initiation. As stated above, in initiating the Federal IDR process, the initiating party will indicate its preferred certified IDR entity in the Notice of IDR Initiation. Under these interim final rules, the party in receipt of the Notice of IDR Initiation may agree or object to the selection of the preferred certified IDR entity identified in the Notice of IDR Initiation. If the non-initiating party in receipt of the Notice of IDR Initiation fails to object within 3 business days of the date of initiation of the Federal IDR process, the preferred certified IDR entity identified in the Notice of IDR Initiation will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the Notice of IDR Initiation timely objects, that party must timely notify the initiating party of the objection, including an explanation of the reason for objecting, and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity. In order to jointly select a certified IDR entity, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services must agree on a certified IDR entity not later than 3 business days after the date of initiation of the Federal IDR process. Due to the short timeframe for this selection, the Departments anticipate that communication between the parties regarding certified IDR entity selection will typically be conducted through electronic mail to the email addresses used to send and receive the Notice of IDR Initiation. The Departments anticipate that most users of the Federal IDR process will be providers, facilities, providers of air ambulance services, plans, and issuers, which are likely to use electronic communications regularly. If both parties agree on and select a certified IDR entity, or fail to agree upon a certified IDR entity within the specified timeframe, the initiating party must notify the Departments by electronically submitting the notice of the certified IDR entity selection or failure to select (as applicable), no later than 1 business day after the end of the 3-business-day period (or in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal. In addition, in instances where the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must notify the Departments through the Federal IDR

portal within the same timeframe that the notice of selection (or failure to select) is required and provide information regarding the lack of applicability. Based upon this information and any additional information requested by the selected certified IDR entity, the selected certified IDR entity will determine whether the Federal IDR process is applicable. The Departments seek comment on this approach and whether any challenges exist in relying solely upon electronic notifications.

The Departments will make available on the Federal IDR portal a list of certified IDR entities among which parties to the Federal IDR process may select, including basic information about the certified IDR entities, such as contact information, certified IDR entity numbers (unique identification numbers assigned to each certified IDR entity by the Departments), websites, and service areas. The Departments seek comment on this approach, including whether additional information about the certified IDR entities should be made public, and whether any challenges exist in relying solely upon electronic notifications.

Under these interim final rules, the selected certified IDR entity must not have a conflict of interest as defined in 26 CFR 54.9816-8T(a)(2), 29 CFR 2590.716-8(a)(2), and 45 CFR 149.510(a)(2). The selected certified IDR entity must also ensure that assignment of personnel to the dispute and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party or type of party (that is, provider, facility, provider of air ambulance services, plan, or issuer) to the determination being disputed other than as outlined under 26 CFR 54.9816-8T(c)(4)(iii), 29 CFR 2590.716-8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii). Also, as agents of the certified IDR entity, personnel responsible for handling individual payment determinations must comply with the certification requirements of these interim final rules as set forth by their principal, the certified IDR entity, in its procedures. Therefore, the personnel assigned to disputes by the certified IDR entity must not have a conflict of interest, as defined by 26 CFR 54.9816-8T(a)(2), 29 CFR 2590.716-8(a)(2), and 45 CFR 149.510(a)(2). In addition, any personnel assigned to the matter must not have been a party to the determination being disputed or an employee or agent of such a party

within the 1 year immediately preceding the dispute resolution assignment, similar to the “revolving door” laws²⁴ laid out in 18 U.S.C. 207(b), 207(c), and 207(e). Under 18 U.S.C. 207(b), 207(c), and 207(e), former officers or employees of the executive branch, including independent agencies, are prohibited from aiding or advising on matters with which they were involved while in the executive branch for 1 year. These interim final rules adopt the same 1-year timeframe by prohibiting former employees’ or agents’ involvement in dispute resolution processes involving former employers for 1 year. The Departments are of the view that this approach provides a reasonable and appropriate standard for preventing conflicts of interest. Although 18 U.S.C. 207(b), 207(c), and 207(e) are typically used in reference to trade or treaty negotiations, the 1-year prohibition is also a standard applied generally to employees of the executive and legislative branches and independent agencies. These statutes represent conflict-of-interest standards that the Departments view as reasonable and appropriate for developing standards for preventing conflicts of interest involving certified IDR entities that are resolving disputes in the Federal IDR process. Certified IDR entities are expected to ensure staff compliance with the standards of these interim final rules, and as such, attestations of no conflict of interest at the organization level are intended also to represent the absence of conflicts of interest among the employees and agents of the certified IDR entity.

The Departments anticipate that certified IDR entities will likely be limited to organizations with sufficient staff who have arbitration and health care claims experience, including entities currently providing services for external review or state IDR determinations. To further ensure that personnel assigned to any determination in the Federal IDR process do not have a conflict of interest, the Departments have included additional safeguards for personnel, as well as an additional requirement that the certified IDR entity have procedures in place to ensure adherence by personnel with these additional safeguards. Accordingly, at the time of application for certification, the IDR entity must attest that it has procedures in place to ensure that no conflicts of interest exist or will exist, as set forth in the discussion of

²⁴ Maskell, J., Post-Employment, “Revolving Door,” Laws for Federal Personnel. Congressional Research Service. 2014. <https://fas.org/sgp/crs/misc/R42728.pdf>.

certification requirements later in this preamble. As an additional requirement, certified IDR entities will have had to submit, as part of their application to be certified IDR entities, policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity procedures in place to inform the Departments of the conflict of interest and mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

If the parties have agreed on a certified IDR entity, the notice of the certified IDR entity selection must include the following information: (1) The name of the certified IDR entity; (2) the certified IDR entity number; and (3) an attestation by both parties (or by the initiating party if the other party has not responded) that the selected certified IDR entity does not have a conflict of interest. The attestation must be submitted based on conducting a conflicts of interest check using information available (or accessible using reasonable means) to the parties (or the initiating party if the other party has not responded) at the time of the selection.

As stated earlier in this preamble, upon receipt of notification that the parties failed to agree on a certified IDR entity, the Departments will select a certified IDR entity. In such instances, the Departments will randomly select a certified IDR entity that charges a fee within the allowed range provided for in guidance and defined further in section III.D.4.viii of this preamble. If there are insufficient certified IDR entities that charge a fee within the allowed range available to adjudicate the payment determination, the Departments will randomly select a certified IDR entity that has received approval to charge a fee outside of the allowed range. The Departments will make the random selection not later than 6 business days after the date of initiation of the Federal IDR process, and will notify the parties of the selection. The Departments considered alternative approaches to randomly selecting a certified IDR entity, including whether the Departments should consider the specific fee of the certified IDR entity or look to other factors, such as how often the certified IDR entity chooses the amount closest to the QPA. Following consideration of various approaches, the Departments have chosen to utilize a random selection method to select a certified IDR entity that charges a fee within the allowed range (or has received approval from the Departments to charge a fee

outside of the allowed range, if there are insufficient certified IDR entities that charge a fee within the allowed range available) and that does not have a conflict of interest with either party. The Departments are of the view that this approach will help ensure that requests for IDR and workload associated with making determinations for such requests are appropriately distributed across the certified IDR entities, will result in an efficient and timely assignment of a certified IDR entity to payment determinations, and will protect against bias in the types of cases a certified IDR entity reviews while encouraging certified IDR entities to charge reasonable fees for their services. Additionally, the Departments are of the view that this approach will provide predictability to the parties regarding the fees they will be expected to pay if they do not select the certified IDR entity. The Departments seek comment on this approach, including whether the random selection method should be limited only to certified IDR entities that charge a fee within the allowed range. The Departments may issue future guidance regarding whether entities that have received approval from the Departments to charge a fee outside of the allowed range may be selected by the Departments under the random selection method.

After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Departments, the certified IDR entity must also review its selection to ensure that it meets the requirements of 26 CFR 54.9816-8T(c)(1)(ii), 29 CFR 2590.716-8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii) related to potential conflicts of interest. If the selected certified IDR entity meets these requirements, the certified IDR entity must attest to meeting these requirements. If the certified IDR entity is unable to attest that it meets these requirements, the certified IDR entity must notify the Departments through the Federal IDR portal within 3 business days, after which the Departments will notify the parties. Upon notification, the parties will have 3 business days to select another certified IDR entity under the process described in 26 CFR 54.9816-8T(c)(1), 29 CFR 2590.716-8(c)(1), or 45 CFR 149.510(c)(1). If the parties notify the Departments that they have not agreed on a certified IDR entity, the Departments may randomly select another certified IDR entity.

The certified IDR entity must also review the information submitted by the parties to determine whether the Federal IDR process applies, including whether an All-Payer Model Agreement

or specified state law applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Departments and the parties within 3 business days of making this determination.

2. Authority To Continue Negotiation

Code sections 9816(c)(2)(B) and 9817(b)(2)(B), ERISA sections 716(c)(2)(B) and 717(b)(2)(B), PHS Act sections 2799A-1(c)(2)(B) and 2799A-2(b)(2)(B), and these interim final rules provide that, in instances in which the parties agree on an amount for a qualified IDR item or service after the Federal IDR process is initiated but prior to a determination by a certified IDR entity, the agreed-upon amount will be treated as the out-of-network rate and will be treated as resolving the dispute. If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing to the Departments the Notice of IDR Initiation, but before the certified IDR entity has made its payment determination, the initiating party must notify the Departments and the certified IDR entity (if selected) by electronically submitting notification of such agreement through the Federal IDR portal as soon as possible but no later than 3 business days after the date of the agreement. As is the case in instances where the parties do not come to an agreement before the certified IDR entity selects the amount submitted by one of the parties, the amount by which this agreed-upon out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment.²⁵ The plan or issuer must pay the balance of the total plan or coverage amount of the agreed-upon out-of-network rate (with any initial payment made counted towards the total plan or coverage payment) to the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. As noted in section III.D.4.viii of this preamble regarding costs of the Federal IDR process, when there is an agreement after initiation and a certified IDR entity is selected but prior to a determination by the certified IDR entity, each party must pay half of the certified IDR entity fee, unless the parties agree otherwise on a method for allocating the applicable fee. In no instance may either party seek

²⁵ See 26 CFR 54.9816-4T, 54.9816-5T, and 54.9817-1T; 29 CFR 2590.716-4, 2590.716-5, and 2590.717-1; and 45 CFR 149.110, 149.120, and 149.130.

additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the QPA. When an agreement is reached, either before or after a certified IDR entity is selected, notification to the Departments must include the out-of-network rate (that is, the total payment amount, including both cost sharing and the total plan or coverage payment) and signatures from an authorized signatory for each party.

3. Treatment of Batched Items and Services

Code section 9816(c)(3), ERISA section 716(c)(3), and PHS Act section 2799A-1(c)(3) direct the Departments to specify criteria under which multiple qualified IDR items and services may be considered jointly as part of one payment determination (batching). Under these interim final rules, multiple claims for qualified IDR items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity (batched items and services) only if certain conditions are met. Batched items and services submitted and considered jointly as part of one payment determination under 26 CFR 54.9816-8T(c)(3)(i), 29 CFR 2590.716-8(c)(3)(i), 45 CFR 149.510(c)(3)(i) are subject to the fee for batched determinations under these interim final rules.

First, the qualified IDR items and services must be billed by the same provider or group of providers or facility or same provider of air ambulance services. Items and services are billed by the same provider or group of providers or facility or same provider of air ambulance services if the items or services are billed with the same National Provider Identifier (NPI) or Taxpayer Identification Number (TIN).

Second, the payment for the items and services would be made by the same group health plan or health insurance issuer.

Third, the qualified IDR items and services must be the same or similar items or services. The definition of a same or similar item or service in these interim final rules is consistent with the definition under the July 2021 interim final rules. The Departments defined a same or similar item or service in 26 CFR 54.9816-6T(a)(13), 29 CFR 2590.716-6(a)(13), and 45 CFR 149.140(a)(13) as those items and services that are billed under the same service code, or a comparable code under a different procedural code system, and the Departments defined the service codes as the code that describes an item or service using

Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

Finally, all the qualified IDR items and services must have been furnished within the same 30-business-day period, or the 90-calendar-day suspension period described later in this preamble. Therefore, if items or services are furnished within the 90-calendar-day suspension period and meet the other applicable requirements, they may be submitted and considered jointly as part of one payment determination by a certified IDR entity, once the suspension period has ended. Under Code section 9816(c)(9), ERISA section 716(c)(9), and PHS Act section 2799A-1(c)(9), the Departments may provide an alternative period to the aforementioned 30-business-day period as determined by the Departments for certain circumstances, such as low-volume items and services. The Departments are using this authority to ensure that items and services delivered during the 90-calendar-day suspension period are eligible for the Federal IDR process and may be included in the same batch.

The Departments are of the view that the approach set forth to allow for batching of multiple qualified IDR items and services will avoid combinations of unrelated claims, providers, facilities, providers of air ambulance services and plans and issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies in the Federal IDR process. The Departments solicit comment on this approach and whether there is a need to prescribe an alternative period for other qualified IDR items and services different from the 30-business-day period discussed earlier in the discussion of the batching requirements and what circumstances should be considered in defining any alternative period.

Additionally, in some cases, a plan or issuer may pay a provider, facility, or provider of air ambulance services a single payment for multiple services an individual received during an episode of care (bundling). In the case of qualified IDR items or services that are billed by a provider, facility, or provider of air ambulance services as part of a bundled arrangement, or where a plan or issuer makes an initial payment as a bundled payment (or specifies that a denial of payment is made on a bundled payment basis), these interim final rules provide that those qualified items or services may be submitted and considered as part of one payment determination by a certified IDR entity (and is subject to the fee for single

determinations under 26 CFR 54.9816-8T(c)(3)(ii), 29 CFR 2590.716-8(c)(3)(ii), 45 CFR 149.510(c)(3)(ii)).

The Departments recognize that certain batched items and services may have different QPAs. For example, if a determination includes multiple batched claims for Service A furnished by Provider B to individuals covered by Issuer C, with some individuals covered by plans in the individual market and others covered by plans in the large group market, there likely would be two different QPAs for the certified IDR entity to consider—one QPA for the services furnished to individuals enrolled in individual market coverage, and one QPA for individuals with large group market coverage. As discussed elsewhere in this preamble, when this is the case, the parties must provide the relevant information for each QPA, and the certified IDR entity must consider each QPA for each item or service separately. However, since batched items and services involve the same or similar medical procedure, batching is likely to reduce redundant IDR proceedings as well as streamline the certified IDR entity's decision-making, as some of the considerations relate to factors not specific to the individual encounter.

The Departments seek comment on all aspects of the criteria for batching claims and bundling, including whether additional conditions should be added to limit batching or whether the conditions should be amended to facilitate broader batching of qualified IDR items and services. The Departments also seek comment on how frequently nonparticipating providers, nonparticipating emergency facilities, or nonparticipating providers of air ambulance services will be reimbursed through a bundled payment and whether allowing items or services included in a bundled payment by a provider or facility to be treated as one payment determination could be used to circumvent the batching requirements by not requiring precise consideration of what specific claims within the batch should be arbitrated and which claims should not, thereby resulting in potential overuse of the Federal IDR process in a manner that creates inefficiencies.

4. Payment Determination

i. Submission of Offers

Code section 9816(c)(5)(B), ERISA section 716(c)(5)(B), and PHS Act section 2799A-1(c)(5)(B) provide that, not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a

qualified IDR item or service, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or provider of air ambulance services must each submit to the certified IDR entity an offer for a payment amount for such qualified IDR item or service. Under these interim final rules, the offer must be submitted not later than 10 business days after the selection of the certified IDR entity and must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, to facilitate the certified IDR entity reporting the offer as a percentage of the QPA to the Departments. Where batched items and services have different QPAs, the parties should provide these different QPAs and may provide different offers for these batched items and services, provided that the same offer should apply for all items and services with the same QPA.

Parties to the Federal IDR process must also submit information requested by the certified IDR entity relating to the offer. The Departments intend for the Federal IDR portal to collect this information as part of the offer submission process, such that certified IDR entities will not have to directly request this information. Providers and facilities must also indicate the size of their practices and facilities at the time the information is submitted. This will enable certified IDR entities to report on the size of the provider practices and facilities, as required under 26 CFR 54.9816-8T(f)(1)(ii), 29 CFR 2590.716-8(f)(1)(ii), and 45 CFR 149.510(f)(1)(ii). Specifically, the provider must specify whether the provider practice or organization has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. Providers and facilities must also provide information on the practice specialty or type, respectively (if applicable). Similarly, plans and issuers must provide the coverage area of the plan or issuer, the relevant geographic region for purposes of the QPA, and, for group health plans, whether they are fully-insured, or partially or fully self-insured.²⁶ FEHB carriers must identify if a particular item or service relates to

FEHB plans. The information such as practice or facility size, coverage area, geographic region, and whether a plan is fully-insured or partially or fully self-insured is required to be submitted as part of an offer so that the certified IDR entities can report this information to the Departments. This information will inform the reports required from the Departments under Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A-1(c)(7). Both parties must submit any other information requested by the certified IDR entity relating to such offer. In addition, parties may submit any information relating to the offer, except that the information may not include information that relates to usual and customary charges, billed amounts, and public payor rates as discussed later in this preamble.

With regard to the number of employees of a provider or facility, the Departments understand that hospitals and facilities may use a variety of methods for staffing, such as through contracting with physicians' practices or foundations whose physicians or medical staff are not considered employees of the hospital or facility. The Departments seek comment on whether additional guidance is needed to account for these situations in the reporting of provider and facility size.

ii. Selection of Offer for Qualified IDR Items or Services That Are Not Air Ambulance Services

These interim final rules provide that, not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the qualified IDR item or service. For each qualified IDR item or service, the amount by which this out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment (with any initial payment made counted towards the total plan or coverage payment). In selecting the offer, the certified IDR entity must presume that the QPA is an appropriate payment amount but must also consider the additional circumstances, following the requirements of 26 CFR 54.9816-8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716-8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), only if the information is submitted by the parties. However, to be considered by the certified IDR entity, information submitted by the parties must be credible and relate to the offer submitted by either party, and must not

include information on the prohibited factors described in 26 CFR 54.9816-8T(c)(4)(v), 29 CFR 2590.716-8(c)(4)(v), or 45 CFR 149.510(c)(4)(v). After considering the QPA, additional information requested by the certified IDR entity from the parties, and all of the credible information that the parties submit that is consistent with the requirements in 26 CFR 54.9816-8T(c)(4)(i)(A), 29 CFR 2590.716-8(c)(4)(i)(A), or 45 CFR 149.510(c)(4)(i)(A), the certified IDR entity must select the offer closest to the QPA, unless the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on the additional circumstances allowed under 26 CFR 54.9816-8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716-8(c)(4)(iii)(B) through (D), or 45 CFR 149.510(c)(4)(iii)(B) through (D) with respect to the qualified IDR item or service. In these cases, or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the items or services, which could be either party's offer.

These interim final rules define information as credible if upon critical analysis the information is worthy of belief and is trustworthy. These interim final rules also specify that a material difference exists where there is substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out of network rate and view the information as showing that the QPA is not the appropriate out-of-network rate under such additional circumstances.

If the certified IDR entity determines that credible information about additional circumstances clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must select the offer that the certified IDR entity determines best represents the appropriate out-of-network rate for the qualified IDR items or services, which could be either party's offer. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must also notify the plan or issuer and the provider or facility of the selection of the offer, and provide the written decision required under 26 CFR 54.9816-8T(c)(4)(vi), 29 CFR 2590.716-8(c)(4)(vi), and 45 CFR 149.510(c)(4)(vi).

²⁶ Pursuant to OPM contracts with FEHB carriers under 5 U.S.C. Ch. 89, 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.

The Departments are of the view that the best interpretation of Code section 9816, ERISA section 716, and PHS Act section 2799A–1 is that when selecting an offer, a certified IDR entity must look first to the QPA, as it represents a reasonable market-based payment for relevant items and services, and then to other considerations. This presumption that the QPA is the appropriate out-of-network rate can be rebutted by presentation of credible information about additional circumstances, following the requirements of 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), that clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate. The statutory text lists the QPA as the first factor that the certified IDR entity must consider in determining which offer to select. The “additional circumstances” that the certified IDR entity must consider if relevant, credible information is provided are described in a separate paragraph, and the certified IDR entity’s consideration of additional circumstances is subject to a prohibition on considering certain factors. Additionally, whereas the statute provides relatively limited guidance on how to consider or define these additional circumstances, the statute sets out detailed rules for calculating the QPA, suggesting that an accurate and clear calculation of the QPA is integral to the application of consumer cost sharing and to the certified IDR entity’s determination of the out-of-network rate. For example, the statute includes a requirement that when plans and issuers do not have sufficient information to calculate their own median contracted rates, they utilize a database free of conflicts of interest.²⁷ Plans and issuers must also provide specific information on how the QPA is calculated to nonparticipating providers and facilities, ensuring that they are aware of how this amount is calculated.²⁸ Plans and issuers are also subject to audit requirements that will be enforced by the Departments to ensure that they follow these rules.²⁹ Cost sharing for participants, beneficiaries, and enrollees for items and services will be based on the recognized amount, which will generally be the QPA for services eligible for the Federal IDR process,

²⁷ Code section 9816(a)(2), (3)(E); ERISA section 716(a)(2), (3)(E), and PHS Act section 2799A–1(a)(2), (3)(E); 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140.

²⁸ *Id.*

²⁹ 86 FR 36872, 36899 (July 13, 2021).

indicating that the QPA is a reasonable out-of-network rate. The Departments are also required to report how payment determinations compare to the corresponding QPA, reflecting that the QPA is a benchmark for determining the appropriate out-of-network rate.³⁰ Taken together, these statutory elements reflect the importance the No Surprises Act assigns to the QPA in the Federal IDR process, and show that the statute contemplates that typically the QPA will be a reasonable out-of-network rate.

The Departments are also of the view that policy considerations support the approach taken under these interim final rules regarding which offer a certified IDR entity must select. Generally, the QPA should reflect standard market rates arrived at through typical contract negotiations and should therefore be a reasonable out-of-network rate under most circumstances. The QPA is generally based on the median of contracted rates, and these contracted rates are established through arms-length negotiations between providers and facilities and plans and issuers (or their service providers). Anchoring the determination of the out-of-network rate to the QPA will increase the predictability of IDR outcomes, which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs, and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, anchoring the determination to the QPA will help limit the indirect impact on participants, beneficiaries, and enrollees that would occur from higher out-of-network rates if plans and issuers were to pass higher costs on to individuals in the form of increases in premiums.

Accordingly, the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate, as discussed earlier in this section of the preamble.

The Departments clarify that it is not the role of the certified IDR entity to determine whether the QPA has been

³⁰ Code section 9816(c)(7)(A)(v), (B)(iii) and (iv); ERISA section 716(c)(7)(A)(v), (B)(iii) and (iv); and PHS Act section 2799A–1(c)(7)(A)(v), (B)(iii) and (iv).

calculated by the plan or issuer correctly, to make determinations of medical necessity, or review denials of coverage.³¹ Rather, the certified IDR entity is responsible for considering only the information presented by the parties to determine whether either party has presented credible information regarding additional circumstances, following the requirements set forth in paragraphs 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), demonstrating that the QPA is materially different from the appropriate out-of-network rate, in order to rebut the presumption that the QPA is the appropriate out-of-network rate. For batched items and services, the certified IDR entity may select different offers, from either or both parties, when the QPAs for the qualified IDR items or services within the batch are different. The certified IDR entity may do so even if it does not select the offer closest to the QPA for a particular qualified IDR item or service due to the factors listed later in this section of the preamble, and instead selects the offer closest to the QPA for other qualified IDR items and services within the batch.

In the Departments’ view, the requirements set forth in these interim final rules regarding which offer a certified IDR entity must select, based on the presumption that the QPA is the appropriate payment amount and on the parties’ ability to rebut that presumption, will help promote efficiency and predictability in the Federal IDR process, and will increase the likelihood that a certified IDR entity will generally select the offer closest to the QPA. While the QPA is the presumptive factor, the Departments are of the view that a clear standard indicating how a certified IDR entity may select an offer that is not closest to the QPA is necessary to help ensure consistency in how different certified IDR entities evaluate offers, which will help ensure that the Federal IDR process yields predictable outcomes and reduces administrative costs. Establishing a standard framework for certified IDR entities to evaluate factors furthers the intent of these interim final

³¹ However, if either the certified IDR entity or one of the parties believes the QPA has not been calculated in accordance with the requirements in 26 CFR 54.9816–6T, 29 CFR 2590.716–6, or 45 CFR 149.140, the Departments encourage the certified IDR entity or the provider or facility to notify the applicable state or federal authority, or submit a complaint against the plan or issuer as set forth in 26 CFR 54.9816–7T, 29 CFR 2590.716–7, or 45 CFR 149.150, as applicable.

rules to create equity and consistency in the Federal IDR process and aligns with other policies set forth in these interim final rules, such as the conflict-of-interest standards and the certification standards for IDR entities. Ensuring that all certified IDR entities apply the same standards will help ensure that the Federal IDR process is appropriately predictable, fair, and equitable.

Although these interim final rules establish the QPA as the presumptive factor, these interim final rules and the underlying statute also specify additional circumstances that certified IDR entities must consider in selecting an offer, if a party submits information about the additional circumstance that the certified IDR entity determines is credible. These interim final rules also require that the parties provide certain information to the certified IDR entity, described previously in this preamble, regarding practice size, practice specialty or type; information about the plan or issuer's coverage area; information about the QPA; and, if applicable, information showing that the Federal IDR process is inapplicable to the dispute. In addition, the certified IDR entity may request additional information relating to the parties' offers and must consider credible information submitted to determine if it demonstrates that the QPA is materially different from the appropriate out-of-network rate (unless the information relates to a factor that the certified IDR entity is prohibited from considering).

Regarding those factors, first, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the level of training, experience, and quality and outcome measurements (such as those endorsed by the consensus-based entity authorized under section 1890 of the Social Security Act) of the provider or facility that furnished the qualified IDR item or service clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. In order for a certified IDR entity to consider this additional information submitted by a party, the credible information must clearly demonstrate that the QPA failed to take into account that the experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient or that the experience or training made an impact on the care that was provided. The Departments are of the view that qualified IDR items or services should not necessitate an out-of-network rate higher than the offer closest to the QPA, simply based on the level of experience

or training of a provider, as this would lead to an increase in prices without a valid reason and does not align with the goals of the No Surprises Act. For instance, the out-of-network payment amount for the simple repair of a superficial wound (CPT codes 12001–12007) in most cases would not necessitate a rate higher than the QPA just because a provider has 30 years of experience versus 10 years of experience. Alternatively, if the plan's or issuer's contracted rates included risk-sharing, bonus, penalty, or other incentive-based or retrospective payments that were excluded for purposes of calculating the QPA for the items and services as required by the July 2021 interim final rules, a party may provide evidence as to why the provider's or facility's quality or outcome measures support an out-of-network rate that is different from the QPA and the certified IDR entity should consider whether this requires selecting an out-of-network rate that is higher (in the case of a bonus) or lower (in the case of a penalty) than the offer closest to the QPA.

Second, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the market share held by the nonparticipating provider or facility or the plan (including, for self-insured plans, the market share of their third-party administrator (TPA) in instances where the self-insured plan relies on the TPA's networks) or issuer in the geographic region in which the qualified IDR item or service was provided, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. Research suggests that the market dominance of a provider or facility, or that of a plan or issuer, can drive reimbursement rates up or down in a given region.³² For instance, a plan or issuer having the majority of the market share in a geographic region may signal a QPA that is unreasonably low, as plans and issuers with a large market share may drive down rates,³³ in which case an out-of-network rate higher than the offer closest to the QPA may be

appropriate. Alternatively, a provider having the majority of the market share in a geographic region may signal a QPA that is unreasonably high, as providers with a large market share may drive up rates, in which case an out-of-network rate lower than the offer closest to the QPA may be appropriate.

Third, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. In many cases, because the plan or issuer is required to calculate the QPA using median contracted rates for service codes, as well as modifiers, if applicable, and because service codes and modifiers reflect patient acuity and the complexity of the service provided,³⁴ these factors will already be reflected in the QPA. Therefore, the Departments anticipate that there would only be rare instances in which the QPA would not adequately account for the acuity of the patient or complexity of the service. For example, if the complexity of a case is an outlier such that the time or intensity of care exceeds what is typical for a service code, the certified IDR entity may conclude that the QPA does not adequately take the factor into account. Similarly, the QPA for a qualified IDR item or service may be considered too high for items or services that become less complex or are furnished more frequently over time, such as items for which the QPA reflects reimbursement for a product with a patent that expires after 2019, in instances where the QPA is based off the median of the contracted rates from 2019. A certified IDR entity may also conclude that the QPA does not adequately account for patient acuity, or the complexity of furnishing the qualified IDR item or service in instances where the parties disagree on what service code or modifier accurately describes the qualified IDR item or service. For instance, the Departments are aware that some plans and issuers review claims and alter the service code or modifier submitted by the provider or facility to another service code or modifier that the plan or issuer determines to be more appropriate (a practice commonly referred to as "downcoding" when the adjustment

³² Schwartz, K., Lopez, E., Rae, M., Neuman, T. What We Know About Provider Consolidation. Kaiser Family Foundation. September 2020. <https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/>.

³³ See Richard M. Scheffler and Daniel R. Arnold. "Insurer Market Power Lowers Prices in Numerous Concentrated Provider Markets." Health Affairs. 2017 36:9, 1539–1546; Glenn Melnick, Yu-Chu Shen and Vivian Wu. "The Increased Concentration Of Health Plan Markets Can Benefit Consumers Through Lower Hospital Prices." Health Affairs 30, no. 9.

³⁴ <https://www.medicalbillingandcoding.org/cpt-modifiers/>.

results in lower reimbursement).³⁵ If a plan or issuer has altered the service code or modifier(s) for a submitted claim and applies a QPA that uses a different service code or modifier(s) than the service code or modifier(s) submitted by the provider or facility, the provider or facility could submit credible information to the certified IDR entity demonstrating that the QPA applied by the plan or issuer to the claim is based on a service code or modifier that did not properly encompass patient acuity, the complexity of furnishing the qualified IDR item or service. If the certified IDR entity agrees that either of the parties have presented credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, and adequately takes into account the considerations allowed under 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), then it could select either offer, but must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.³⁶

Fourth, to the extent credible information is submitted by a party, the certified IDR entity must also consider whether the credible information about the teaching status, case mix, and scope of services of the nonparticipating facility, clearly demonstrates that the QPA is materially different from the

³⁵ The Departments clarify that the July 2021 interim final rules do not require the plan or issuer to calculate the participant's, beneficiary's, or enrollee's cost sharing using a QPA for the service code submitted by the provider or facility. The plan or issuer could instead calculate the participant's, beneficiary's, or enrollee's cost sharing using a QPA for the service code that the plan or issuer determined was more appropriate. However, the QPA methodology under 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140 requires plans and issuers to calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service. A plan or issuer would be considered out of compliance with these requirements if the plan or issuer calculated a QPA using a service code that does not reasonably reflect the furnished item or service.

³⁶ The Departments note that in instances in which the certified IDR entity selects an offer based on a determination that a service code other than the one upon which the QPA was based more accurately describes the qualified IDR item or service, neither the plan or issuer nor provider or facility is permitted to adjust the participant's, beneficiary's, or enrollee's cost-sharing amount. The cost-sharing amount remains the same as originally calculated in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and 45 CFR 149.110(b)(3)(ii) and (iii); 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.717–1(c)(1) and (2), and 45 CFR 149.120(c)(1) and (2); or 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and 45 CFR 149.130(b)(1) and (2).

appropriate out-of-network rate for the qualified IDR item or service. Similar to the other factors, it is the view of the Departments that the QPA, which is intended to reflect the market-driven rate, should be considered the prevailing rate unless a party provides credible information that the characteristic of the teaching status, case mix, or scope of services of the nonparticipating facility was in some way critical to the delivery of the qualified IDR item or service, and not adequately accounted for in the QPA, thereby rebutting the presumption that the QPA is the appropriate out-of-network rate. For example, a certified IDR entity could consider the trauma level of a hospital when the dispute involves trauma care or qualified IDR items or services that could not be performed at a lower-level hospital, but only to the extent the QPA does not otherwise reflect this factor. The Departments seek comment on whether additional requirements should be considered to address any potentially abusive scenarios, including scenarios in which parties could potentially distort information that informs the enumerated considerations, such as overestimating the teaching experience of providers at the facility or upcoding the costs for items or services, and seek comment on the potential for gaming of the Federal IDR process.

Fifth, to the extent credible information is submitted by a party, the certified IDR entity must also consider whether the credible information about any demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services or the plan or issuer, as applicable, to enter into network agreements and, if applicable, contracted rates between the provider or facility and the plan or issuer, as applicable during the previous 4 plan years, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. For example, a certified IDR entity must consider what the contracted rate might have been had the good faith negotiations resulted in the nonparticipating provider, facility, or provider of air ambulance services being in-network, if a party is able to provide related credible information of good faith efforts or the lack thereof.

Beyond these enumerated factors, the certified IDR entity must also generally consider additional information submitted by a party, provided the information is credible and relates to the

offer submitted by either party. The certified IDR entity is not permitted to consider that information if it includes information on factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). This prohibition is discussed further in the next section of this preamble.

The Departments intend to provide additional guidance to certified IDR entities as necessary to clarify how the allowable factors should be considered and seek comment on this approach, including the appropriateness and scope of the factors previously discussed.

iii. Selection of Offer for Qualified IDR Services That Are Air Ambulance Services

The process for a certified IDR entity to select an offer in a dispute related to qualified IDR services that are air ambulance services is essentially the same as the process applicable to disputes related to qualified IDR items or services that are not air ambulance services. As with disputes related to qualified IDR items or services that are not air ambulance services, in determining which offer to select, these interim final rules provide that the certified IDR entity must consider the QPA for the applicable year for the qualified IDR services that are air ambulance services. However, Code section 9817(b)(5)(C), ERISA section 717(b)(5)(C), PHS Act section 2799A–2(b)(5)(C), and these interim final rules specify additional circumstances, in addition to the QPA, that the certified IDR entity must also consider in making the determination for air ambulance services, to the extent the parties provide credible information on such criteria. As with qualified IDR items or services, the certified IDR entity should only consider this information to the extent the certified IDR entity determines that either party submitted credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. If a party presents credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must consider the additional circumstances.

To the extent credible information is submitted by a party, the certified IDR entity must consider whether credible information about the quality and outcomes measurements of the provider of air ambulance services that furnished the services clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. Additionally, to the extent credible

information is submitted by a party, the certified IDR entity must consider whether credible information about the acuity of the condition of the participant, beneficiary, or enrollee receiving the services, or the complexity of providing the services to the participant, beneficiary, or enrollee, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. Further, to the extent credible information is submitted by a party, the certified IDR entity must consider credible information submitted by a party about whether the level of training, experience, and quality of medical personnel that furnished the air ambulance services clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the air ambulance services. To the extent a party submits any such credible information, the certified IDR entity must also consider whether credible information about the ambulance vehicle type, including the clinical capability level of the vehicle, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the air ambulance services. In considering the ambulance vehicle type, the certified IDR entity may not consider whether the air ambulance is fixed wing or rotary wing, because the QPA will reflect this difference, as different service codes are used to bill for air ambulance services depending on whether fixed wing or rotary wing vehicles are used. Instead, the certified IDR entity should consider air ambulance vehicle type only to the extent that it is not already taken into account by the QPA.

To the extent a party submits any such credible information, the certified IDR entity must also consider whether credible information about the population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier³⁷), clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for a particular air ambulance service. Under the July 2021 interim final rules, the QPA is calculated by reference to the geographic region, which for air ambulance services distinguishes between one region containing all metropolitan statistical areas (as

described by the U.S. Office of Management and Budget (OMB) and published by the U.S. Census Bureau) in a 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). If these geographic regions do not provide sufficient information, the QPA is calculated in reference to Census divisions, with one region consisting of all metropolitan statistical areas in each Census division, and one region consisting of all other portions of the Census division, determined at the point of pick-up. Therefore, the QPA for these geographic regions may already reflect the population density of the pick-up location. Nevertheless, in certain circumstances, the QPA for air ambulance services may not adequately capture the population density, due to additional distinctions, such as between metropolitan areas within a state, or between rural and frontier areas. To the extent that there is credible information about additional circumstances clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate for a particular air ambulance service, the certified IDR entity must consider these distinctions.

Finally, to the extent credible information is submitted by a party, the certified IDR entity must consider whether credible information about demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements, as well as contracted rates between the provider and the plan or issuer, as applicable, during the previous 4 plan years, clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate for such air ambulance services.

As with qualified IDR items or services that are not air ambulance services, the certified IDR entity must begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate for the air ambulance service under consideration and select the offer closest to the QPA, unless credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, or unless the offers are equally distant from the QPA but in opposing directions. In those cases, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR items or services, which could be either party's offer.

iv. Prohibition on Consideration of Certain Factors

Code section 9816(c)(5)(D), ERISA section 716(c)(5)(D), PHS Act section 2799A-1(c)(5)(D), and these interim final rules provide that the certified IDR entity may not consider certain factors in determining which offer is the out-of-network rate. First, the certified IDR entity may not consider usual and customary charges. This term, also known as usual, customary and reasonable charges, refers to the amount providers in a geographic area usually charge for the same or similar medical service.³⁸ This provision also prohibits consideration of payment or reimbursement rates expressed as a proportion of usual and customary charges. Second, certified IDR entities cannot consider the amount that would have been billed to either a plan or issuer, or a participant, beneficiary, or enrollee by a provider, facility, or provider of air ambulance services if the provider, facility, or provider of air ambulance services were not subject to a prohibition on balance billing. The Departments recognize that 45 CFR 149.410, 149.420, and 149.440 prohibit providers, facilities, and providers of air ambulance services from billing participants, beneficiaries, or enrollees for the full charge for items and services to which these provisions apply, but do not limit the amount that may be billed to the plan or issuer. However, the Departments are of the view that the intent of Code section 9816(c)(5)(D), ERISA section 716(c)(5)(D), and PHS Act section 2799A-1(c)(5)(D) is to prohibit the certified IDR entity from considering the billed charge for a qualified IDR item or service. Therefore, the Departments interpret this prohibition to include consideration of billed charges to the plan or issuer for the qualified IDR item or service. Finally, certified IDR entities must not consider payment or reimbursement rates payable by a public payor, in whole or in part, for items and services furnished by the providers, facilities, or providers of air ambulance services. This prohibition includes payments or reimbursement rates under the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act, the Children's Health Insurance Program under title XXI of the Social

³⁷ For these purposes, the term "frontier" should be understood as including those ZIP codes where the point of pick-up is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density (also known as super rural ZIP codes for purposes of determining ground ambulance base rates). See 42 CFR 414.610(c)(5)(ii) and 42 CFR 414.626(c)(1)(ii).

³⁸ See Uniform Glossary of Coverage and Medical Terms, available at <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/sbc-uniform-glossary-of-coverage-and-medical-terms-new.pdf> and <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Uniform-Glossary-01-2020.pdf>.

Security Act, and the TRICARE program under chapter 55 of title 10, United States Code, chapter 17 of title 38, United States Code. This prohibition also applies to payment rates for demonstration projects under section 1115 of the Social Security Act, as these are payment or reimbursement rates payable by a public payor. This provision prohibits consideration of payment or reimbursement rates expressed as a proportion of rates payable by public payors. Thus, the certified IDR entity must not consider, for example, which offer is closest to 150 percent of the Medicare reimbursement rate for a certain item or service.³⁹ The Departments solicit comment regarding whether any additional guidance or clarification is needed on these prohibited factors.

v. Written Decision

Once the certified IDR entity has made a determination, the certified IDR entity must provide the underlying rationale for its determination in a written decision submitted to the parties and the Departments. The certified IDR entity must submit the decision and the underlying rationale through the Federal IDR portal in a form and manner specified by the Departments in guidance. This rationale will inform the reports required from the Departments under Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A-1(c)(7), and will assist in ensuring that the certified IDR entities comply with the requirements of this process, including the requirements of 26 CFR 54.9816-8T(c)(4)(iii), 29 CFR 2590.716-8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii). If a certified IDR entity does not choose the offer closest to the QPA, the written decision's rationale must include a detailed explanation of the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate.

³⁹ The Departments recognize that contracted rates are frequently based off a percentage of the Medicare payment rate. The Departments clarify that even in instances where the QPA is calculated using contracted rates that are expressed as a proportion of rates payable by a public payor (or other prohibited considerations), the certified IDR entity is required to consider the QPA. In the Departments' view, this does not constitute consideration of the payment or reimbursement rate payable by a public payor.

v. Effect of Determination

Code section 9816(c)(5)(E), ERISA section 716(c)(5)(E), PHS Act section 2799A-1(c)(5)(E), and these interim final rules provide that a determination made by a certified IDR entity is binding upon all parties involved, in the absence of fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim. A certified IDR entity's determination is not subject to judicial review, except as set forth in 9 U.S.C. 10(a)(1)-(4).⁴⁰

Under Code section 9816(c)(5)(E)(ii), ERISA section 716(c)(5)(E)(ii), PHS Act section 2799A-1(c)(5)(E)(ii), and these interim final rules, when a certified IDR entity makes a determination, the party that submitted the initial Notice of IDR Initiation may not submit a subsequent Notice of IDR Initiation involving the same other party with respect to a claim that is the same as or similar to a qualified IDR item or service that was the subject of the initial determination during the 90-calendar-day period following the initial determination. The Departments interpret the 90-day period in the statute to refer to 90 calendar days. The Departments are of the view that this interpretation balances the statutory intent to provide for a "cooling-off" period between disputes that relate to the same or similar items or services while ensuring that the initiating party is able to resolve outstanding payment disputes through the Federal IDR process as soon as permitted under the statute. The Departments interpret the statutory phrase of "such item or service" in this context to refer to the same or similar item or service, in order to maintain consistency with the statutory provisions related to the QPA and the provisions allowing batching of items and services. Additionally, such an interpretation clarifies the meaning of the statutory provisions at Code section 9816(c)(5)(E)(iii), ERISA section 716(c)(5)(E)(iii), and PHS Act section 2799A-1(c)(5)(E)(iii), which allow subsequent submission of such an item or service only if the open negotiation period ended during such a 90-day period (as the open negotiation period for the particular item or service under

⁴⁰ Subparagraphs (1) through (4) of 9 U.S.C. 10(a) provide that courts may vacate an arbitration: where the award was procured by corruption, fraud, or undue means; where there was evident partiality or corruption in the arbitrators; where the arbitrators were guilty of misconduct in refusing to postpone the hearing, in refusing to hear evidence pertinent and material to the controversy; or of any other misbehavior prejudicing the rights of the parties; or where the arbitrators exceeded their powers, or so imperfectly executed them that a mutual, final, and definite award was not made.

dispute would have already ended). For claims for the same or similar item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process for the items and services affected by the suspension. For these items or services, the initiating party must submit the Notice of IDR Initiation within 30 business days following the end of the 90-calendar-day suspension period, as opposed to the standard 4-business-day period following the end of the open negotiation period. The 30-business-day period begins on the day after the last day of the 90-calendar-day period.

The plan or issuer must make any additional payment, if applicable, of the amount of the offer selected by the certified IDR entity directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. This amount will be the offer selected, reduced by the sum of any initial payment the plan or issuer has paid to the provider, facility, or provider of air ambulance services and any cost sharing paid or owed by the participant, beneficiary, or enrollee to the provider, facility, or provider of air ambulance services. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant, beneficiary, or enrollee, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. This difference must be paid directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity. The Departments note that this determination of the out-of-network rate does not change the participant's, beneficiary's, or enrollee's cost sharing, which is based on the recognized amount. The cost-sharing amount remains the same as originally calculated in accordance with 26 CFR 54.9816-4T(b)(3)(ii) and (iii), 29 CFR 2590.716-4(b)(3)(ii) and (iii), and 45 CFR 149.110(b)(3)(ii) and (iii); 26 CFR 54.9816-5T(c)(1) and (2), 29 CFR 2590.716-5(c)(1) and (2), and 45 CFR 149.120(c)(1) and (2); or 26 CFR 54.9817-1T(b)(1) and (2), 29 CFR 2590.717-1(b)(1) and (2), and 45 CFR 149.130(b)(1) and (2).

vi. Recordkeeping Requirement

These interim final rules require that the certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for 6 years. The 6-year

recordkeeping requirement is similar to other recordkeeping requirements under the Code, ERISA, and the PHS Act. For example, independent review organizations involved in the Federal external review process under 26 CFR 54.9815–2719, 29 CFR 2590.715–2719, and 45 CFR 147.136 must retain records for 6 years. This recordkeeping requirement will help ensure that state and Federal oversight agencies are able to audit past determinations of certified IDR entities and that parties are able to obtain records of the determinations. Certified IDR entities must make these records available for examination by all parties to the dispute, except when disclosure would violate state or Federal privacy laws and regulations, as well as to state or Federal oversight agencies upon request for oversight purposes.

vii. Costs of the Federal IDR Process and Payment

At the time that a certified IDR entity is selected by both of the parties or by the Departments, each party to a determination must pay to the certified IDR entity the administrative fee due to the Departments for participating in the Federal IDR process. At the time of submission of the offer by each party to a determination, the certified IDR entity fee must be paid to the certified IDR entity. Each party will be able to view the certified IDR entity fees and administrative fees in the Federal IDR portal when engaging in the certified IDR entity selection process. As discussed later in this preamble, certified IDR entities must set the certified IDR entity fee within a pre-determined range (or as otherwise approved by the Departments) specified by the Departments through guidance. The Departments anticipate issuing this guidance annually. For a discussion of the considerations the Departments will review when setting the certified IDR entity fee range, see section III.D.5 of this preamble.

These interim final rules require each party to pay the entire certified IDR entity fee at the time the parties provide their offer under 26 CFR 54.9816–8T(c)(4)(i), 29 CFR 2590.716–8(c)(4)(i), and 45 CFR 149.510(c)(4)(i). Certified IDR entities are required to hold these funds in a trust or escrow account until the certified IDR entity makes a determination of the out-of-network rate, or in instances in which the parties agree on an out-of-network rate, until the Departments notify the certified IDR entity that it may remit the funds as specified in these interim final rules. The certified IDR entity may (but is not required to) accrue interest on the funds. The certified IDR entity is not

required to remit any accrued interest to any other party. Within 30 business days of making the determination, the certified IDR entity must refund to the prevailing party the amount the party submitted for the certified IDR entity fee. The certified IDR entity will retain the certified IDR entity fee submitted by the non-prevailing party, as the non-prevailing party is required to pay the certified IDR entity fee. In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute. In these cases, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. The Departments are of the view that this approach reduces the administrative burden of fee collections and ensures payment of certified IDR entities. This approach also eliminates any concerns that certified IDR entities will make determinations based on which party is more likely to pay the certified IDR entity fee. The Departments may issue additional guidance if abusive situations or other issues related to the payment of the administrative fee or the certified IDR entity fee arise. The Departments also solicit comment on whether additional requirements, including procedures to offset against or make adjustments to amounts owed under a payment determination, are necessary to ensure payment or collection of the administrative fee and the certified IDR entity fee.

If the parties negotiate an out-of-network rate before the certified IDR entity makes a determination, the certified IDR entity is required to return half of each party's payment for the certified IDR entity fee, unless directed otherwise by both parties to distribute the total amount of that refund in different shares.

Under Code section 9816(c)(8), ERISA section 716(c)(8), PHS Act section 2799A–1(c)(8), and these interim final rules, each party to a determination must pay an administrative fee for participating in the Federal IDR process. The statute further indicates that the administrative fee must be paid to the Departments at the time and in the manner specified by the Departments. These interim final rules require each party to pay the administrative fee to the certified IDR entity at the time the certified IDR entity is selected, regardless of whether that certified IDR

entity was selected by the parties or by the Departments. Having the certified IDR entity collect both the administrative fee and the certified IDR entity fee will help ensure efficiency by streamlining the process and will facilitate administrative convenience for the parties and the Departments. These interim final rules also specify that the administrative fee is non-refundable, even in instances where the parties negotiate an out-of-network rate before the certified IDR entity makes a determination or where the certified IDR entity determines that the case does not qualify for the Federal IDR process. Code section 9816(c)(8)(B), ERISA section 716(c)(8)(B), and PHS Act section 2799A–1(c)(8)(B) specify that the administrative fee is established such that the total amount of fees is approximately equal to the amount of expenditures estimated by the Departments in carrying out the Federal IDR process. Because the Departments expect that a large part of the expenditures in carrying out the Federal IDR process will come from the initiation of the Federal IDR process, the Departments will have incurred expenditures in instances in which the parties reach an agreement before the certified IDR entity makes a determination or in which the certified IDR entity determines that the case does not qualify for the Federal IDR process, and thus, it is appropriate that the parties should still be expected to pay the fee.

As explained in the following section on certification, the certified IDR entity must remit the administrative fee to the Departments at the time and in the manner specified in guidance. The administrative fee amount will be established in guidance published by the Departments in a manner so that the total administrative fees collected by the certified IDR entities and remitted to the Departments during a calendar year are approximately equal to the estimated amount of expenditures by the Departments for that calendar year in carrying out the Federal IDR process. In setting the administrative fee, the Departments will consider the estimated costs for the Departments to administer the Federal IDR process for the following calendar year, including the staffing and contracting costs related to certifying and providing oversight to certified IDR entities; the costs of developing and publishing reports as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2; the costs of collecting the administrative fees from certified IDR

entities; and the cost of maintaining the Federal IDR portal. In future years, such projected costs will be informed by the actual costs incurred by the Departments to date to administer the Federal IDR process. The Departments expect that certain resources related to the Federal IDR process will also be used for the patient-provider dispute resolution process, such as the Federal IDR portal, certain staffing, and contracts. In setting the administrative fee, the Departments will consider the expected volume for the Federal IDR process and the patient-provider dispute resolution process and apportion the IDR administrative fee such that it reflects the appropriate usage of the Federal IDR process by providers, facilities, providers of air ambulance services, plans, and issuers.

5. Certification of IDR Entities

Under Code section 9816(c)(4), ERISA section 716(c)(4), and PHS Act section 2799A-1(c)(4), an IDR entity must meet certain standards and be certified by the Departments to be selected for the Federal IDR process. Consistent with these provisions, these interim final rules provide that an IDR entity must provide through the Federal IDR portal written documentation to the Departments that demonstrates the entity satisfies certain standards and procedures outlined in these interim final rules and set forth in guidance issued by the Departments. Specifically, the Departments will indicate through guidance the types of documentation that should be submitted for each certification standard, in what manner they should be submitted, and how the documentation will be reviewed for certification. An IDR entity that satisfies the standards in the interim final rules and guidance issued by the Departments will be provided a certified IDR entity number and will be certified for a 5-year period, subject to the petition and revocation process, discussed later in this preamble.⁴¹ Once certified, the certified IDR entity must continue to satisfy these requirements.

IDR entities will be expected, as part of their application for certification, to submit general information about their organization, including contact information, Taxpayer Identification Number (TIN), and website information, as well as the service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to

apply to operate in all states or self-limit to a particular subset of states. Further, anyone submitting the application for certification must have the legal and financial authority to bind the IDR entity. An IDR entity that the Departments certify must enter into an agreement with the Departments. That agreement will include specified provisions encompassed by these interim final rules, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

In order to be certified, an IDR entity must possess (directly or through contracts or other arrangements) and demonstrate sufficient arbitration and claims administration of health care services, managed care, billing, coding, medical, and legal expertise. With regard to medical expertise, where the payment determination depends on the patient acuity or the complexity of furnishing the qualified IDR item or service, or the level of training, experience, and quality and outcome measurements of the provider or facility that furnished the qualified IDR item or service, the IDR entity should have available medical expertise with the appropriate training and experience in the field of medicine involved in the qualified IDR item or service. Additionally, the IDR entity must employ (directly or through contracts or other arrangements) sufficient personnel to make determinations within the 30 business days allowed for such determinations. To satisfy this standard, the written documentation the IDR entity submits must include a description of its organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations. The Departments considered requiring IDR entities to have personnel (either hired directly or through a contract) with air space law knowledge for making determinations related to air ambulance cases, but are concerned that such a requirement may limit the number of eligible entities and increase the likelihood of conflicts of interests in air ambulance cases. The Departments seek comment on whether IDR entities should be required to have air space law knowledge for IDR entity certification to make determinations for air ambulance cases.

Next, an IDR entity must also maintain a current accreditation from a

nationally recognized and relevant accreditation organization, such as URAC, or ensure that its personnel otherwise possess the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the AAA, the AHLA, or a similar organization). This requirement will ensure the IDR entity has the operational ability to perform its primary functions as set forth in the No Surprises Act and these interim final rules. States have imposed similar requirements on independent review organizations for external review processes under PHS Act section 2719 (which is incorporated by reference into Code section 9815 and ERISA section 715), or for their state IDR processes. Similar to independent review organizations, certified IDR entity personnel should have the skills and training necessary to conduct unbiased and impartial determinations between plans or issuers and providers, facilities, or providers of air ambulance services, and similar billing, coding, and medical expertise. The Departments expect that many of the organizations with current experience in arbitration or dispute resolution will already have such accreditation and will employ personnel with relevant experience. The Departments seek comment on whether any additional accreditation or training standards would meet this requirement, including whether additional flexibility is needed to help encourage innovation in the provision of IDR services and new entrants as IDR entities that may be certified for the Federal IDR process.

Additionally, as a condition of certification, the IDR entity must have a process to ensure that no conflicts of interest exist between the parties and the personnel the certified IDR entity assigns to each dispute, and to screen for any material relationships between the parties and the personnel assigned to each dispute. This process will allow certified IDR entities to comply with the requirements of 26 CFR 54.9816-8T(c)(1)(ii), 29 CFR 2590.716-8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii).

While conducting the Federal IDR process, a certified IDR entity will be entrusted with IIHI. Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A-1(c)(4)(A)(v) require a certified IDR entity to maintain the confidentiality of IIHI obtained in the course of conducting payment determinations. This IIHI is often protected under Federal and state law, but certain laws, such as the privacy and security regulations promulgated

⁴¹ As discussed in the section on Economic Impact and Paperwork Burden, the Departments estimate there will be 50 IDR entities that will seek certification by the Departments.

under HIPAA, as amended, may not apply to IIHI when it is held by a certified IDR entity.

Therefore, these interim final rules specify that a certified IDR entity must provide written documentation to the Departments that demonstrates that the certified IDR entity satisfies, among other things, the confidentiality standards set forth in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). These provisions include standards for certified IDR entities to maintain the confidentiality of IIHI obtained in the course of conducting the Federal IDR process. Because IIHI is sensitive, private information about consumers and their health, including information that is identifiable to a particular individual, IIHI warrants strong protection by the parties that will be handling this information. Therefore, the Departments are of the view that certified IDR entities must have procedures in place to protect consumers from improper storage, use, handling, or transmission of this information. The confidentiality standards in these interim final rules are informed by the privacy, security, and breach notification regulations issued under HIPAA and the HITECH Act, because the Departments are of the view that these provisions are industry standards.⁴² Drawing from those standards for these interim final rules promotes continuity in the way consumer information is protected and secured throughout systems involved in health care. The Departments have drawn mainly from relevant HIPAA standards because these are the predominant federal standards that apply to identifiable consumer health information, when possessed by some of the parties to the Federal IDR process. Therefore the Departments are of the view that these standards are the most appropriate privacy standards for certified IDR entities. The Departments have tailored these requirements to the particular functions of certified IDR entities to ensure that they have clear, workable, and appropriate standards to implement.

These interim final rules set forth the confidentiality requirements applicable to certified IDR entities and include provisions regarding privacy, security, and breach notification. The Departments begin by discussing the general privacy requirement in 26 CFR 54.9816–8T(e)(2)(v)(A), 29 CFR 2590.716–8(e)(2)(v)(A), and 45 CFR 149.510(e)(2)(v)(A) that specify that a

certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI only to perform two categories of activities, described in 26 CFR 54.9816–8T(e)(2)(v)(A)(1) through (2), 29 CFR 2590.716–8(e)(2)(v)(A)(1) through (2), and 45 CFR 149.510(e)(2)(v)(A)(1) through (2): (1) To perform the certified IDR entity's required duties under these sections of the interim final rules; and (2) to perform functions related to carrying out additional obligations as may be required under applicable Federal or state laws or regulations.

Additionally, certified IDR entities are required to maintain the security of the IIHI they obtain by ensuring the confidentiality of all IIHI they create, obtain, maintain, store, and transmit; protecting against any reasonably anticipated threats or hazards to the security of this information; protecting against any reasonably anticipated unauthorized uses or disclosures of this information; and by ensuring compliance by any of their personnel, including their contractors and subcontractors (as applicable), assigned to a payment determination. To satisfy this requirement, certified IDR entities are required to have policies and procedures in place to properly use and disclose IIHI, identify when IIHI should be destroyed or disposed of, properly store and maintain confidentiality of IIHI that is accessed or stored electronically, and identify the steps the certified IDR entities will take in the event of a breach regarding IIHI. The Departments based these requirements on the similar rule applicable to HIPAA covered entities under 45 CFR 164.306(a)(1), but because the rule for HIPAA covered entities applies specifically with regard to electronic protected health information (PHI), the requirements in these interim final rules specify that certified IDR entities must ensure the confidentiality of all IIHI they create, obtain, maintain, store, or transmit in accordance with Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v). A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in these interim final rules.

The Departments also require certified IDR entities to securely destroy or dispose of IIHI in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier. In

determining what is appropriate and reasonable, certified IDR entities should assess potential risks to participant, beneficiary, or enrollee privacy, as well as consider such issues as the form, type, and amount of IIHI to be disposed. The Departments are of the view that 6 years is a reasonable timeframe for destruction of such information since relevant business procedures should be complete well before this deadline, including IDR payment determinations and certified IDR entity compliance with the Departments' audits as applicable. Furthermore, the 6-year timeframe matches the record retention requirements for certified IDR entities under these interim final rules as well as other record retention requirements under ERISA. These standards are also similar to HIPAA Security Rule requirements⁴³ under 45 CFR 164.310(d)(2)(i) and (ii), except that the Departments have tailored the requirements in section 26 CFR 54.9816–8T(e)(2)(v)(B)(4), 29 CFR 2590.716–8(e)(2)(v)(B)(4), and 45 CFR 149.510(e)(2)(v)(B)(4) to apply to IIHI.

Next, the Departments require certified IDR entities to develop and utilize secure electronic interfaces when transmitting IIHI electronically, including through data transmission with the Federal IDR portal, and between disputing parties during the Federal IDR process and the certified IDR entity. In addition, the Departments are of the view that certified IDR entities must have in place requirements for their personnel, including their contractors and subcontractors (as applicable), similar to those required under HIPAA Rules to make sure IIHI is only handled by appropriate staff who are trained to handle IIHI, and that proper protocol is followed if a breach of IIHI occurs.

Finally, 26 CFR 54.9816–8T(e)(2)(v)(D), 29 CFR 2590.716–8(e)(2)(v)(D), and 45 CFR 149.510(e)(2)(v)(D) require that all confidentiality requirements applicable to certified IDR entities also apply to certified IDR entities' contractors and subcontractors with access to IIHI performing any duties related to the Federal IDR process. For example, if a breach rises to the level of requiring a breach notification, the contractor or subcontractors must notify the certified IDR entity to inform it of the risk assessment results, and the certified IDR entity must notify the provider, facility,

⁴² 45 CFR part 160 subpart A and subparts A, C, D, and E of part 164.

⁴³ U.S. Dept. of Health and Human Servs., Office for Civil Rights, "The HIPAA Privacy and Security Rules: Frequently Asked Questions About the Disposal of Protected Health Information," available at <https://www.hhs.gov/sites/default/files/disposalfaq.pdf>.

or provider of air ambulance services; plan and issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible, as required by these interim final rules.

In addition to the privacy and security requirements discussed in this section of this preamble, these interim final rules contain breach notification requirements, similar to the HIPAA breach notification standards (the "HIPAA Notification Rule") at 45 CFR 164.402 and 164.404, to address steps that a certified IDR entity must take following the discovery of a breach of unsecured IIHI as defined in these interim final rules. The Departments are of the view that adopting breach notification standards similar to the HIPAA breach notification standards for certified IDR entities provides important protections for IIHI. For purposes of these interim final rules, the Departments made changes from the HIPAA breach notification standards to account for IIHI and certified IDR entities, as opposed to PHI and covered entities, in accordance with Code section 9816(c)(4)(C), ERISA section 716(c)(4)(C), and PHS Act section 2799A-1(c)(4)(C). The Departments require a certified IDR entity, upon discovery of a potential breach of unsecured IIHI, to conduct a risk assessment to determine the probability that the security or privacy of IIHI has been compromised based on at least the nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; the unauthorized person who used the IIHI or to whom the disclosure was made; whether the IIHI was actually acquired or viewed; and the extent to which the risk to the IIHI has been mitigated. The Departments also require a breach to be treated as discovered by the certified IDR entity as of the first day on which such breach is known to the certified IDR entity or, by exercising reasonable diligence, should have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence should have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity.

The Departments are also including requirements for timing, content, and method of providing the breach notification in these interim final rules. Under these provisions, a certified IDR entity must provide notification without unreasonable delay and in no case later

than 60 calendar days after the discovery of the breach. The Departments are of the view that 60 calendar days provides sufficient time for a certified IDR entity to discover a potential breach, conduct a risk assessment, and send notification as required in these interim final rules, in line with the requirements in 45 CFR 164.404 that allow up to 60 calendar days for such a notification to be sent. Since a condition for IDR entity certification involves submission of policies and procedures to: Properly create, obtain, maintain, store, or transmit IIHI in accordance with Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A-1(c)(4)(A)(v); monitor, periodically assess, and update the security controls and related system risks to ensure the continued effectiveness of these controls; and guard against, detect, and report malicious software, the Departments are of the view that 60 calendar days are sufficient for proper identification, risk assessment, and notification of a breach.

When a certified IDR entity sends a breach notification, the content must include similar information as that required under 45 CFR 164.404, but focused on IIHI. Certified IDR entities must include, to the extent possible, the identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach; a brief description of the breach, including the date of the breach and the date of the discovery of the breach, if known; a description of the types of unsecured IIHI that were involved in the breach (for example, whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved); a brief description of what the certified IDR entity is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address. The Departments are of the view that this level of detail is necessary for full transparency for those who are potentially affected by such a breach.

Finally, a certified IDR entity must submit such notification in written form (in clear and understandable language) either on paper, electronically through the Federal IDR portal, or by email to the Departments; the plan, issuer or FEHB carrier; the provider, facility, or provider of air ambulance services; and,

when possible, each individual whose unsecured protected IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach. The Departments understand that a certified IDR entity may not have access to contact information for each individual whose unsecured protected IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to a breach. In these cases, IDR entities must work with issuers, plans, providers, and facilities to ensure that these individuals are appropriately notified.

The Departments seek comment on the confidentiality requirements enumerated in 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v), which are based on certain provisions of the HIPAA Rules, and whether any additional or different protections are warranted.

Additionally, the certified IDR entity must ensure the fiscal integrity and stability of its organization. In order to meet this standard, the IDR entity must demonstrate that it has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents and to assure fiscal integrity and accountability for all fees received and held. To demonstrate financial stability, IDR entities must also submit 3 years of financial statements, or other documentation that demonstrates fiscal stability as directed by the Departments if 3 years of financial statements are unavailable. This financial disclosure requirement is informed by similar requirements under the Sarbanes-Oxley Act.⁴⁴ The Departments are of the view that, because the Sarbanes-Oxley Act represents the primary standard for corporate disclosure of financial information, it is appropriate to mirror its standard as a means of ensuring certified IDR entity compliance with the statutory requirements related to fiscal integrity. The Departments are also of the view that the disclosure of these financial statements will enable the Departments to assess whether the IDR entity is financially viable and capable of maintaining its operations, independent of any future revenue earned under the Federal IDR process as a certified IDR entity.

As a condition of certification, an IDR entity must indicate to the Departments the fees it intends to charge for payment determinations, which are limited to a fixed fee amount for single

⁴⁴ Public Law 107-204, available at <https://www.govinfo.gov/content/pkg/PLAW-107-publ204/html/PLAW-107publ204.htm>.

determinations (including determinations for bundled arrangements) and a separate fixed fee amount for batched determinations under paragraph (c)(3)(i) of these interim final rules. These fixed fees must be within a range set forth in guidance by the Departments, unless the IDR entity receives written approval from the Departments for a fee outside that range. The Departments are of the view that setting a range of permitted flat amounts, including a lower and upper limit, will permit certified IDR entities to charge a reasonable certified IDR entity fee for IDR payment determinations, while also making IDR costs clear to parties in advance of the Federal IDR process. Setting a minimum and a maximum rate will mitigate potential concerns regarding overuse of the Federal IDR process due to low fees and potential concerns regarding overcharging by certified IDR entities. For batched items and services, setting a separate range that is higher to account for the potential for a larger number of claims and increased complexity will help ensure that certified IDR entities are compensated adequately for their services. The certified IDR entity may update its fees and seek approval from the Departments to charge a flat rate beyond the upper or lower limits for fees annually, as provided in guidance.

The Departments considered whether to allow certified IDR entities to set their fees without limitations and also considered imposing anti-abuse provisions to prevent certified IDR entities from charging unreasonable amounts, while also taking into account the statutory intent to discourage the overuse of the Federal IDR process and incentivize IDR entity participation in the process. The Departments are of the view, however, that requiring certified IDR entities to set fees within fixed ranges will reduce the potential for excessive certified IDR entity fees that could result in inflated health care and insurance costs that could ultimately be passed on to consumers. The Departments are also setting a lower bound for certified IDR entity fees to ensure that certified IDR entity fees do not lead to the overuse of the Federal IDR process, thereby encouraging parties to exhaust other paths to agreement, such as open negotiation, before entering the Federal IDR process.

In setting the allowable certified IDR entity fee range, the Departments will consider current IDR entity fees for state-managed IDR processes that are similar to the Federal IDR process. Based on the Departments' research on existing IDR processes in states that

have implemented similar surprise billing legislation, IDR entity fees generally range from \$300–\$600 per payment determination.⁴⁵ The Departments acknowledge that in some states, individual arbitrators charge as little as \$270 and as much as \$6,000 per arbitration.⁴⁶ However, the Departments are of the view that such drastic ranges of IDR entity fees risk inflating costs of care that could ultimately be passed on to consumers.

The Departments will also consider the anticipated time and resources needed for certified IDR entities to meet the requirements of these interim final rules, such as the time and resources needed to obtain certification, making payment determinations (including determining whether the dispute belongs in the Federal IDR process), data reporting, and audits. The Departments will also consider factors such as the anticipated volume of payment determinations under the Federal IDR process and adequacy of the Federal IDR process capacity to efficiently handle the volume of IDR initiations and payment determinations. The Departments will review and update the allowable fee range annually based on these factors and the impact of inflation and other cost increases. The Departments seek comment on these factors and any additional factors that should be considered when determining the range for allowable certified IDR entity fees.

The certified IDR entity may not charge a fee that is beyond the upper or lower limits for fees set forth in annual guidance published by the Departments as approved fixed fees, unless the IDR entity or certified IDR entity requests and can provide justification for the higher or lower fee, and the Departments provide written approval for the certified IDR entity to charge a fee beyond the upper or lower limits for fees set forth in guidance. For example, if the IDR entity or certified IDR entity is able to show that, due to matters the Department has not considered, the cost of making determinations under 26 CFR 54.9816–8T(c)(4), 29 CFR 2590.716–8(c)(4), and 45 CFR 149.510(c)(4) will be higher than the upper limit for fees set forth in guidance, the certified IDR entity may charge a higher fee for determinations in that calendar year with the Departments' written approval

⁴⁵ Hoadley, J., and Maanasa, K. "How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payment in Surprise Billing." To the Point 9(blog), Commonwealth Funds, Feb. 27, 2020. <https://doi.org/10.26099/pqt4-vy24>.

⁴⁶ <https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/amp/>.

in accordance with 26 CFR 54.9816–8T(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), 45 CFR 149.510(e)(2)(vii). Certified IDR entities will not be permitted to vary their fees from any approved higher fees during the year for which such higher fees were approved.

Specifically, in order for the certified IDR entity to receive the Departments' written approval to charge a fee beyond the upper or lower bounds for fees as set forth in guidance, the IDR entity or certified IDR entity must submit a written proposal that includes: (1) The alternative flat fee the IDR entity or certified IDR entity believes is appropriate; (2) a description of the circumstances that require the alternative flat fee; and (3) a description of how the alternative flat fee will be used to mitigate such circumstances. A fee other than the higher (or lower) fee previously approved, including one outside the allowable range, will be permitted only upon the Departments' written approval to charge the fee documented in the IDR entity's or certified IDR entity's written proposal. The Federal IDR portal will provide the functionality for IDR entities and certified IDR entities to request a fixed fee beyond the lower and upper limits set forth in guidance. As discussed earlier in this preamble, in instances where the disputing parties do not select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range as provided for in guidance by the Departments. Only if there are insufficient certified IDR entities that charge a fee within the allowed range available to make the payment determination will the Departments select a certified IDR entity that charges a fee that has been approved by the Department but that is outside the allowed range.

A certified IDR entity must also have procedures in place to retain the certified IDR entity fees paid by both parties at the initiation of the Federal IDR process in a trust or escrow account separate from other funds and to return the certified IDR entity fees paid by the prevailing party of an IDR payment determination, or a portion of the fees paid by both parties should they agree on an out-of-network rate through ongoing open negotiations, within 30 business days of the determination, as specified in these interim final rules. The certified IDR entity may (but is not required to) accrue interest on the funds held in a trust or escrow account and is not required to include accrued interest with the returned fee. Additionally, the IDR entity must also have a procedure in place to retain the administrative fee

required under 26 CFR 54.9816–8T(e)(2)(ix), 29 CFR 2590.716–8(e)(2)(ix), and 45 CFR 149.510(e)(2)(ix), and to remit it to the Departments in accordance with the timeframe and procedures set forth in guidance.

As a condition of certification, the IDR entity must show that it is able to conduct the Federal IDR process as required under these interim final rules. As part of this requirement, the IDR entity must have processes and procedures in place to ensure that it will not make a determination under the Federal IDR process with respect to which the certified IDR entity would not be eligible for selection due to a conflict of interest.

Therefore, in order to be certified, an IDR entity must provide written documentation that shows the IDR entity satisfies certain standards related to conflicts of interest. Under 26 CFR 54.9816–8T(e)(3)(i), 29 CFR 2590.716–8(e)(3)(i), and 45 CFR 149.510(e)(3)(i) the IDR entity must attest that it does not have a conflict of interest as defined in 26 CFR 54.9816–8T(a)(2)(iv), 29 CFR 2590.716–8(a)(2)(iv), and 45 CFR 149.510(a)(2)(iv). Additionally, to be certified, an IDR entity must demonstrate that it has procedures in place to ensure that the specific personnel assigned to a payment determination do not have conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination. This requirement is similar to the requirements set forth in 18 U.S.C. 207(b) and, as discussed earlier in this section of the preamble, provides a reasonable and appropriate standard for preventing conflicts of interest.⁴⁷

Finally, to preserve the integrity of the Federal IDR process, following certification, if a certified IDR entity, at any time acquires control of, becomes controlled by, or comes under common control with any entity described in paragraphs 26 CFR 54.9816–8T(e)(3)(i), 29 CFR 2590.716–8(e)(3)(i), and 45 CFR 149.510(e)(3)(i), the certified IDR entity must notify the Departments in writing no later than 3 business days after the acquisition or exercise of control. As the certified IDR entity would no longer meet the certification criteria, it will have its certification revoked under the processes set forth in 26 CFR 54.9816–8T(e)(6), 29 CFR 2590.716–8(e)(6), and 45 CFR 149.510(e)(6) (including the prohibition on accepting new payment

determinations). The Departments seek comment on whether any additional protections are necessary.

Certified IDR entities must also adhere to audit standards set forth in these interim final rules and by the Departments in guidance to ensure that certified IDR entities are adhering to the requirements of these interim final rules, including those regarding certification as a certified IDR entity and those outlining how entities must conduct payment determinations as defined in Code section 9816(c), ERISA section 716(c), and PHS Act section 2799A–1(c). To ensure adherence, the Departments intend to perform audits on a select number of certified IDR entities. Certified IDR entities may be randomly selected by the Departments for an audit or selected based upon stakeholder complaints (including those received in connection with a petition for revocation of certification) received by the Departments. Resulting findings may be used for revocation of certification or in re-certification decisions made by the Departments.

Finally, the IDR entity must collect and provide the information required to be reported to the Departments under 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), and 45 CFR 149.510(f) and report such information about the Federal IDR process on a timely basis to the Departments in the form and manner provided by the Departments in guidance.

6. Petition for Denial or Revocation of IDR Entity Certification

An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for the denial of a certification of an IDR entity or a revocation of a certification of a certified IDR entity for failure to meet the requirements of Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), or these interim final rules, through the Federal IDR portal in the form and manner set forth in guidance to be issued by the Departments. The petitioner must submit a written petition to the Departments that identifies the IDR entity seeking certification or the certified IDR entity that is the subject of the petition and outlines the reasons for the petition. The petition must also specify whether the petition seeks denial or revocation of a certification and must be signed by the petitioner. The petitioner may use the standard petition notice issued by the Departments and submit any supporting documentation for consideration by the Departments. The Departments will make public the list of IDR entities

seeking certification, as well as the list of certified IDR entities, to help facilitate the petition process. Petitioners submitting a petition for denial of a certification will have 5 business days from the announcement that an IDR entity is seeking certification to submit the written petition. This 5-business-day period is applicable until the Departments issue guidance outlining a different period for petitions for a denial of certification.

The Departments will acknowledge receipt of the petition within 10 business days of receipt. If, after review, the Departments find that the petition adequately shows a failure to comply with the requirements of Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), or these interim final rules, the Departments shall notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following this notification, the IDR entity seeking certification or the certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Departments will review the response (if any) and determine whether a denial or a revocation of certification is warranted. The decision will be subject to the appeal requirements of 26 CFR 54.9816–8T(e)(6)(v), 29 CFR 2590.716–8(e)(6)(v), and 45 CFR 149.510(e)(6)(v). If the Departments, after reviewing a certified IDR entity's response, find that the petition shows a failure to comply with the requirements of Code section 9816(c), ERISA section 716(c), or PHS Act section 2799A–1(c) but have not yet made a final decision pending appeal, a certified IDR entity may continue to work on previously assigned determinations. However, the certified IDR entity will not be permitted to accept new requests for IDR payment determinations unless and until the Departments issue a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted. If the entity is seeking certification, and the Departments find that denying certification is warranted, then the Departments will deny certification.

The IDR entity certification requirements included in these final rules are developed to ensure the integrity of the Federal IDR process. Failure to meet these standards puts at risk the Departments' ability to ensure providers, facilities, providers of air ambulance services, plans, and issuers can avail themselves of an equitable and efficient process. Therefore, the Departments may deny an IDR entity

⁴⁷ 18 U.S.C. 207 provides for certain restrictions on former officers, employees, and elected officials of the executive and legislative branches of the federal government.

certification if, during the process of certification, including as a result of a petition, the Departments determine the IDR entity fails to meet the applicable standards required for certification. Additionally, these interim final rules set forth other reasons that certification may be denied. For example, if the IDR entity has knowingly committed or participated in fraudulent or abusive activities such as by submitting to the Departments fraudulent data or information during the certification process or submitting data or information that the IDR entity knows to be false, certification may be denied. Another situation in which an IDR entity's application for certification might be denied for knowingly committing or participating in fraudulent or abusive activities would be when an IDR entity has engaged in fraudulent practices related to activities conducted outside the Federal IDR process. Additionally, if the IDR entity submits information as part of the certification process that demonstrates that the IDR entity cannot fulfill the responsibilities required of certified IDR entities, certification will be denied.

Also, to the extent the IDR entity has failed to comply with requests for information from the Departments as part of the certification process, certification may be denied. The Departments expect that as part of the certification process, the Departments may need to contact the IDR entities and request clarifying information.

Moreover, if in conducting payment determinations, including those conducted outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality, certification may be denied. With respect to certified IDR entities applying for recertification, the Departments will also consider whether, in conducting payment determinations under the Federal IDR process, the certified IDR entity has met the standards applicable to those payment determinations. It is the Departments' view that, although certain conduct (for example, unethical conduct regarding payment determinations conducted outside the Federal IDR process) may not constitute a violation of the Federal IDR process, this conduct could indicate that the IDR entity may be unable to comply with the requirements of the Federal IDR process. Additionally, to the extent it is otherwise determined that the IDR entity is not fit or qualified to make determinations, certification may be denied.

If the Departments find, after review of the evidence, that a certified IDR entity is no longer qualified to make determinations due to an audit, a petition, or otherwise, the certification of the IDR entity may be revoked. A certified IDR entity's certification may be revoked prior to the end of the 5-year term for the following reasons.

First, a certified IDR entity's certification may be revoked prior to the end of the 5-year term if the Departments determine that the certified IDR entity has a pattern or practice of noncompliance with any of the requirements applicable to certified IDR entities under the Federal IDR process.

Second, if the certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process, its certification may be revoked prior to the end of the 5-year term. For example, if a certified IDR entity consistently fails to meet the deadline for rendering its decisions as set forth in these interim final rules, its certification may be revoked. Also, if a certified IDR entity repeatedly fails to check for a conflict of interest between itself, its personnel, and third parties with which the certified IDR entity contracts, and the disputing parties, its certification may be revoked prior to the end of the 5-year term.

Third, if the certified IDR entity no longer meets the applicable certification standards set forth in these interim final rules under 26 CFR 54.9816-8T(e)(1), 29 CFR 2590.716-8(e)(1), and 45 CFR 149.510(e)(1), its certification may be revoked prior to the end of the 5-year term.

Fourth, if the certified IDR entity has committed or knowingly participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Departments, its certification may be revoked prior to the end of the 5-year term. A situation in which an IDR entity's application for certification might be revoked for knowingly committing or participating in fraudulent or abusive activities would be where a certified IDR entity has engaged in fraudulent practices related to activities conducted outside the Federal IDR process.

Fifth, if the certified IDR entity no longer possesses the financial viability to provide dispute resolution under the Federal IDR process, its certification may be revoked prior to the end of the 5-year term. The Departments are of the view that a certified IDR entity must possess the requisite level of fiscal stability that demonstrates the entity is a viable entity able to continue to carry out the Federal IDR process in a timely and efficient manner as set forth in the

No Surprises Act and these interim final rules.

Sixth, if the certified IDR entity has failed to comply with requests from the Departments made as part of an audit, including submission of records, its certification may be revoked prior to the end of the 5-year term. The audit process plays an important part in helping to ensure that certified IDR entities are abiding by the requirements set forth in these interim final rules. In order to ensure that the Federal IDR process is fair, equitable, and does not have an inflationary effect on health care costs due to certified IDR entities failing to properly apply the factors as set forth in these interim final rules, the Departments are of the view that it will be prudent to review certified IDR entities' processes and procedures. Therefore, failure to comply with such audits will be a basis for revocation of certification.

Seventh, if it is otherwise determined that the certified IDR entity is no longer fit or qualified to make payment determinations, its certification may be revoked prior to the end of the 5-year term. For example, the Departments may determine that an IDR entity is unfit to participate in the Federal IDR process if the IDR entity is engaged in actions that risk the integrity of the Federal IDR process.

If the Departments make a preliminary determination that an IDR entity's certification should be denied or that a certified IDR entity's certification should be revoked, the Departments will issue a notice of proposed denial to the IDR entity seeking certification or a notice of proposed revocation to the certified IDR entity within 10 business days of the preliminary determination. The notice will include the proposed effective date of denial or revocation, explain the reasons for denial or revocation, and provide an opportunity to request an appeal of the proposed denial or revocation. The Departments seek comment on whether final rules should include additional bases for revocation. The Departments also seek comment on whether certain facts and circumstances should result in immediate revocation of certification of the certified IDR entity and reassignment of any pending payment determinations prior to completion by that certified IDR entity.

In order for an IDR entity that has received a notice of proposed denial or certified IDR entity that has received a notice of proposed revocation to request an appeal of its proposed denial or revocation, as applicable, it must submit its request for an appeal to the Departments within 30 business days of

the date of the notice and in the manner prescribed by the notice. During the period when the IDR entity or certified IDR entity may appeal the denial or revocation, the Departments will not issue a notice of final denial or revocation. Furthermore, until a final decision on the appeal is rendered by the Departments, the certified IDR entity may complete any open IDR payment determinations assigned to it at the time of notification, but may not receive new assignments until a final decision regarding revocation has been made. Relevant information to support a request for appeal may include a statement of the facts, law, and arguments that negate or mitigate the evidence provided in support of the IDR entity's certification denial or the revocation of a certified IDR entity's certification, including a description of the actions the certified IDR entity or IDR entity has taken, is taking, or intends to take to cure the failures identified in the notice (if possible) and to prevent the failures from reoccurring.

In the event the IDR entity or certified IDR entity does not timely submit a request for appeal of the proposed denial or revocation, the Departments will issue a final notice of denial or revocation as described under 26 CFR 54.9816-8T(e)(6)(ii), 29 CFR 2590.716-8(e)(6)(iii), and 45 CFR 149.510(e)(6)(iii). Similarly, if the Departments reach a final determination upon appeal that the IDR entity's certification is denied or the certified IDR entity's certification is revoked, the Departments will issue a final notice of denial or revocation including an explanation of the reasons for final denial or revocation and consequences of such denial or revocation of certification to the IDR entity and the petitioner. Upon final notice of denial or revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. If, following a final decision denying or revoking a certification, the IDR entity comes into compliance with the requirements of 26 CFR 54.9816-8T(e), 29 CFR 2590.716-8(e), and 45 CFR 149.510(e), the IDR entity may again apply for certification beginning on the 181st calendar day after the date of the final notice of denial or revocation. The Departments are of the view that providing a 180-calendar-day cooling-off period provides adequate time for an IDR entity to correct and improve its processes to comply with the standards of these interim final rules, ensuring that IDR entities are afforded an opportunity to

come into compliance and re-apply for certification. The Departments are using calendar days for this standard rather than business days for consistency with other, similar suspension periods, such as those in the guaranteed availability provisions under PHS Act section 2702(d)(2), as implemented at 45 CFR 147.104(c)(2).

The Departments will monitor the implementation of the Federal IDR process, as well as the petition process, to determine whether certified IDR entities are abiding by the applicable requirements. The Departments seek comment on any additional requirements regarding denial and revocation, and whether other steps may be required to prevent patterns and practices of noncompliance.

7. Reporting of Information Relating to the Federal IDR Process for Qualified IDR Items and Services That Are Not Air Ambulance Services

Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A-1(c)(7) direct the Departments to make certain information related to the Federal IDR process available on a public website for each calendar quarter in 2022 and each calendar quarter in subsequent years. Code section 9816(c)(7)(C), ERISA section 716(c)(7)(C), and PHS Act section 2799A-1(c)(7)(C) specifically require the certified IDR entities to provide information to the Departments as determined necessary to carry out the requirements regarding publication of information related to the Federal IDR process. To ensure the Departments have the information needed to satisfy this requirement, these interim final rules provide that, within 30 business days of the close of each month, each certified IDR entity must report certain data and information in a form and manner specified by the Departments for qualified IDR items and services furnished on or after January 1, 2022 that were subject to payment determinations. Such reporting will be required as an ongoing condition of certification. The Departments anticipate that much of this information will be captured by the certified IDR entities during the normal course of the Federal IDR process. As discussed elsewhere in this preamble, the Departments expect that many of these reporting requirements will be captured as information submitted through the Federal IDR portal. To the extent the necessary information is captured directly through the portal, the Departments do not intend for certified IDR entities to report duplicative information. The Departments will

provide additional guidance to certified IDR entities on their reporting obligations.

Under these interim final rules, the certified IDR entity must report the number of Notices of IDR Initiation submitted to the certified IDR entity during the immediately preceding month. In instances where the provider or facility submits the initial Notice of IDR Initiation, the certified IDR entity must submit to the Departments information on the size of the provider practice and the size of the facilities submitting Notices of IDR Initiation. Specifically, the certified IDR entity must specify whether the provider practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101-500 employees or more than 500 employees. For facilities, the certified IDR entity must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101-500 employees, or more than 500 employees. This information will allow the Departments to determine whether smaller providers and facilities have the resources necessary to make use of the Federal IDR process and will assist the Departments in determining whether larger organizations may have an unfair advantage in the process. It also will assist the Departments in determining the effect of the Federal IDR process on horizontal and vertical integration of providers and facilities, and in reporting on this effect to Congress, as required by statute in Code section 9816(c), ERISA section 716(c), PHS Act section 2799A-1(c), and section 109 of the No Surprises Act.

Additionally, with respect to Notices of IDR Initiation submitted during the immediately preceding month, certified IDR entities must report the number of Notices of IDR Initiation for which a final determination was made by the certified IDR entity under these interim final rules. The certified IDR entity also must report a description of the qualified IDR items and services for each Notice of IDR Initiation submitted during the immediately preceding month for which a payment determination was made. This information should include the relevant billing and service codes, such as the CPT, HCPCS, DRG codes, or National Drug Codes (if applicable). The certified IDR entity must also report the relevant geographic region for purposes of the QPA for the qualified IDR items and services with respect to which the Notice of IDR Initiation was provided.

These interim final rules also require that for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately

preceding month, the certified IDR entity must report the offers submitted by each party expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, and whether the offer selected by the certified IDR entity was submitted by the plan or issuer, or the provider or facility. Where batched items and services have multiple QPAs, the certified IDR entities must report the offer as a percentage of each QPA that applied with respect to the batched items and services to which the offer applied. For example, if one batch of services included services to which two different QPAs applied, and the parties each submitted the same offer for all batched services, then the certified IDR entity must report each offer as a dollar amount and as a percentage of both QPAs. However, if instead each party submitted two offers—one that applied to the services for which one QPA applied and one that applied to the services for which the other QPA applied—then the certified IDR entity is required to report each offer separately and must express each offer as a dollar amount and as a percentage of the applicable QPA. As discussed earlier in this preamble, in making the determination, the certified IDR entity must provide a rationale for its decision, including the extent to which a decision relied on criteria other than the QPA. The certified IDR entity must also report the number of times the out-of-network rate determined exceeded the QPA. Where the QPA differs within a group of batched items and services, the certified IDR entity also must include whether the out-of-network rate (or various out-of-network rates, when more than one out-of-network rate is selected) exceeded the applicable QPA.

For each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must also report certain additional information on the parties involved. Specifically, the certified IDR entity must report the practice specialty or type of each provider or facility involved in furnishing the qualified IDR items or services at issue with respect to the determination. Additionally, the certified IDR entity must provide each party's name and address.

The certified IDR entity also must report the number of business days taken between the selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month. Finally, the certified

IDR entity must report the total amount of certified IDR entity fees paid to the certified IDR entity during the immediately preceding month. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to the prevailing party or the administrative fees that are collected on behalf of the Departments.

8. Reporting of Information Relating to the Federal IDR Process for Qualified IDR Items or Services That Are Air Ambulance Services

Under Code section 9817, ERISA section 717, and PHS Act section 2799A–2, the Departments must publish on a public website for each calendar quarter in 2022 and each calendar quarter in a subsequent year certain information regarding disputes about air ambulance services that differs from the information required under Code section 9816, ERISA section 716, and PHS Act section 2799A–1 regarding disputes for other items and services to which the protections of the No Surprises Act apply. Therefore, 26 CFR 54.9817–2T(b)(3), 29 CFR 2590.717–2(b)(3) and 45 CFR 149.520(b)(3) specify that in applying the requirements of 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), and 45 CFR 149.510(f) to air ambulance services, the information that the certified IDR entity must report within 30 business days of the close of each month, for services furnished on or after January 1, 2022, in a form and manner specified by the Departments, is as follows.

The certified IDR entity must report the number of Notices of IDR Initiation submitted to the certified IDR entity that pertain to air ambulance services during the immediately preceding month. Additionally, with respect to Notices of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must report the number of Notices of IDR Initiation for which there was a determination under 26 CFR 54.9816–8T(c)(4)(ii), 29 CFR 2590.716–8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii), as applied by 26 CFR 54.9817–2T(b)(1), 29 CFR 2590.717–2(b)(1), and 45 CFR 149.520(b)(1) for air ambulance services. The certified IDR entity must also report the number of times the out-of-network rate determined (or agreed to) exceeded the QPA for air ambulance services.

With respect to each Notice of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must provide a description of each air ambulance service, including the relevant billing and service codes and point of pick-up

(as defined in 42 CFR 414.605) for the services included in such Notice of IDR Initiation. For each Notice of IDR Initiation, the certified IDR entity must also provide the amount of the offer submitted by a plan or issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount. Of these amounts, the certified IDR entity must also indicate whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer or by the provider of air ambulance services and the amount of the offer so selected, expressed as both a dollar amount and a percentage of the QPA. The certified IDR entity must also report the rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria listed under 26 CFR 54.9817–2T(b)(2), 29 CFR 2590.717–2(b)(2), and 45 CFR 149.520(b)(2). Additionally, the certified IDR entity must identify the air ambulance vehicle type, including whether the vehicle is fixed wing or rotary wing (information which should be included in the relevant service code), and the clinical capability level of the vehicle (if the parties have provided such information). The certified IDR entity must also report the identity of each plan or issuer, and provider of air ambulance services, with respect to the Notice of IDR Initiation submitted during the immediately preceding month. Specifically, each certified IDR entity must provide each party's name and address, as applicable. The certified IDR entity must report the number of business days taken between the selection of the certified IDR entity and the certified IDR entity's selection of the payment amount. Finally, the certified IDR entity must also report the total amount of certified IDR entity fees paid to the certified IDR entity for the immediately preceding month. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to prevailing parties or the administrative fees that are collected on behalf of the Departments.

9. Extension of Time Periods for Extenuating Circumstances

Under Code section 9816(c)(9), ERISA section 716(c)(9), PHS Act section 2799A–1(c)(9), and these interim final rules, the time periods specified in these interim final rules (other than the timing of the payments, including, if applicable, payments to the provider, facility or provider of air ambulance services) may be extended in the case of

extenuating circumstances at the Departments' discretion. The Departments may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by plans, issuers, providers, facilities, and providers of air ambulance services to comply with the terms of these interim final rules. Additionally, for the extension to be granted, the parties must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable. Parties may request an extension by submitting a Request for Extension due to Extenuating Circumstances through the Federal IDR portal, including an explanation about the extenuating circumstances that require an extension and why the extension is needed.

E. Applicability of the Rules Regarding the Federal IDR Process

The applicability of these interim final rules with respect to the items and services, plans and issuers, and providers, facilities, and providers of air ambulance services subject to these interim final rules, parallels that of the July 2021 interim final rules to ensure that the surprise billing protections of the No Surprises Act are implemented in a consistent manner. Finally, these interim final rules provide standards for certifying IDR entities, and standards for certified IDR entities. Accordingly, these interim final rules amend 26 CFR 54.9816-2T, 29 CFR 2590.716-2, and 45 CFR 149.20 to include references to 26 CFR 54.9816-8T and 54.9817-2T; 29 CFR 2590.716-8 and 2590.717-2; and 45 CFR 149.510 and 149.520 to ensure that the items and services, as well as entities subject to the balance billing protections under the July 2021 interim final rules, are eligible for the Federal IDR process under these interim final rules. The Departments solicit comment on whether any differences or departures from the approach taken in the July 2021 interim final rules are warranted.

These interim final rules implementing the Federal IDR process 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 and to certified IDR entities, health care providers and facilities, and providers

of air ambulance services beginning on January 1, 2022. The interim final rules regarding IDR entity certification at 26 CFR 54.9816-8T(a), 26 CFR 54.9816-8T(e), 29 CFR 2590.718-8(a), 29 CFR 2590.718-8(e), 45 CFR 149.510(a) and 45 CFR 149.510(e), are applicable beginning on October 7, 2021 so that the Departments can begin certifying IDR entities before the Federal IDR process becomes applicable. 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, 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 PHS Act sections 2799A-1, 2799A-2, and 2799A-7 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) for plan years beginning on or after January 1, 2022. In addition, these interim final rules implementing the Federal IDR process 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 grandmothered or transitional plans). These interim final rules implementing the Federal IDR process do not apply to health reimbursement arrangements (HRAs), or other account-based group health 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 these plans makes concepts related to surprise billing, including the IDR process, inapplicable. Additionally, the Departments expect

that account-based group health plans typically will be integrated with other coverage that will have protections against surprise billing (such as individual coverage HRAs) or will be otherwise exempt from these requirements (such as excepted benefit HRAs). Therefore, under these interim final rules, these requirements do not apply to individual coverage HRAs and other account-based plans, consistent with the existing applicability provisions in 26 CFR 54.9816-2T, 29 CFR 2590.716-2, and 45 CFR 149.20 with respect to other requirements in 26 CFR part 54, 29 CFR subpart D, and 45 CFR part 149. The Departments note that by statute certain plans and coverage are not subject to the interim final rules implementing the Federal IDR process. This includes a plan or coverage consisting solely of excepted benefits⁴⁸ as well as short-term, limited-duration insurance as defined under PHS Act section 2791(b)(5).⁴⁹ Excepted benefits are described in Code section 9832, ERISA section 733 and PHS Act section 2791. Under PHS Act section 2791(b)(5), short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is therefore exempt from these interim final rules regarding the Federal IDR process and the statutory provisions these interim final rules implement. In addition, these interim final rules do not apply to retiree-only plans, because ERISA section 732(a) and Code section 9831(a) generally provide that part 7 of ERISA and chapter 100 of the Code respectively do not apply to plans with fewer than two participants who are current employees (including retiree-only plans, which cover fewer 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.⁵⁰ HHS intends to continue to follow this same approach, including with respect to the new market reforms established in the No Surprises Act.

⁴⁸ Code section 9831, ERISA section 732, and PHS Act section 2722; 26 CFR 54.9831-1(c), 29 CFR 2590.732(c), and 45 CFR 146.145(b).

⁴⁹ 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103.

⁵⁰ 75 FR 34537, 34540 (June 17, 2010).

IV. External Review and Section 110 of the No Surprises Act

Section 110 of the No Surprises Act states that “[i]n applying the provisions of section 2719(b) of the [PHS Act] to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of HHS, Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717 or PHS Act section 2799A–1 or 2799A–2, including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.” The statute defines the terms group health plan and health insurance issuer by reference to PHS Act section 2791, ERISA section 733, and Code section 9832, as applicable.

These interim final rules implement section 110 of the No Surprises Act in two ways. First, these interim final rules amend the scope of claims eligible for external review set forth in the regulations implementing PHS Act section 2719 to include adverse benefit determinations related to compliance with the surprise billing and cost-sharing protections under the No Surprises Act. Additionally, these interim final rules clarify the scope of external review in light of new surprise billing and cost-sharing protections under the No Surprises Act and provide examples of which types of adverse benefit determinations will be eligible for external review. Second, these interim final regulations extend the external review requirement to grandfathered health plans and health insurance issuers for adverse benefit determinations involving items and services covered by requirements of Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2, as added by the No Surprises Act. The Departments solicit comment on whether and to what extent additional guidance or changes to the existing regulations are needed to protect participants, beneficiaries, and enrollees from surprise medical bills, consistent with section 110 of the No Surprises Act.

A. Scope of Claims Eligible for External Review

Under PHS Act section 2719 and its implementing regulations, non-grandfathered group health plans and

health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with any applicable state external review process, if that process includes, at a minimum, the consumer protections set forth in the NAIC Uniform External Review Model Act.⁵¹ However, if the state external review process does not meet this standard, or if a plan or issuer is not subject to state insurance regulation, the plan or issuer must comply with the Federal external review process, as described in 26 CFR 54.9815–2719(d), 29 CFR 2590.715–2719(d), and 45 CFR 147.136(d).

State external review processes that meet the minimum standards must provide for the external review of adverse benefit determinations based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as a rescission of coverage. In the Departments’ view, the scope of claims eligible for external review under state processes that meet the minimum standards for approval is substantially similar to the scope of claims eligible for external review under the Federal process.

In 2010, the Departments issued interim final rules that set forth the original scope of claims eligible for external review under the Federal external review process.⁵² Specifically, any adverse benefit determination (including final internal adverse benefit determinations) could be reviewed unless it was related to a participant’s or beneficiary’s failure to meet the requirements for eligibility under the terms of a group health plan (for example, worker classification and similar issues were not within the scope of the Federal external review process). In response to stakeholder comments, the Departments issued an amendment in 2011 suspending the original rule and narrowing the scope to claims that involve: (1) Medical judgment (including, but not limited to, those based on the plan’s or issuer’s requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, or its determination that a treatment is experimental or investigational), as determined by the

external reviewer; and (2) a rescission of coverage (whether or not the rescission has any effect on any particular benefit at the time).⁵³ The Departments finalized the narrowed scope in the 2015 final rules.⁵⁴

Although the scope of Federal external review was narrowed in comparison to the scope as outlined in the 2010 interim final regulations, the Departments note that the scope of claims that are eligible for external review in general is broad, as many adverse benefit determinations involve medical judgment. The 2015 final regulations issued by the Departments include the following examples: (1) Whether treatment by a specialist is medically necessary or appropriate (pursuant to the plan’s standard for medical necessity or appropriateness); (2) whether treatment involved “emergency care” or “urgent care,” affecting coverage or the level of coinsurance; (3) a determination that a medical condition is a preexisting condition; (4) whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan’s wellness program; and (5) whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act.⁵⁵

The Departments have similarly provided a number of additional examples in preambles to rulemaking under PHS Act section 2719 to provide further clarification on the broad scope of the external review process. In the preamble to interim final rules issued in 2011, the Departments stated that examples of medical judgment would include the appropriate health care setting for providing medical care to an individual (such as outpatient versus inpatient care or home care versus rehabilitation facility); a plan’s general exclusion of an item or service (such as speech therapy), if the plan covers the item or service in certain circumstances based on a medical condition (such as, to aid in the restoration of speech loss or impairment of speech resulting from a medical condition); and the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified in the recommendation or guideline of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or the Health

⁵¹ Available at <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/naic-uniform-review-model-act.pdf>.

⁵² 75 FR 43329 (July 23, 2010).

⁵³ 76 FR 37207 (June 10, 2011).

⁵⁴ 80 FR 72191 (Nov. 18, 2015).

⁵⁵ 26 CFR 54.9815–2719(d)(1); 29 CFR 2590.715–2719(d)(1); 45 CFR 147.136(d)(1).

Resources and Services Administration.⁵⁶ In the preamble to final rules issued in 2015, the Departments also clarified that issues related to how a claim is coded may also involve medical judgment because “[m]edical judgment is necessary to determine whether the correct code was used in the patient’s case.”⁵⁷

Consistent with this principle, the Departments are of the view that many claims that result in an adverse benefit determination involving items and services subject to the surprise billing and cost-sharing protections under the No Surprises Act generally would be eligible for external review under the current scope as specified in the 2015 final regulations. However, as stated above, section 110 of the No Surprises Act directs the Departments to require the external review process under PHS Act section 2719 to apply with respect to any adverse determination by a plan or issuer under PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817, including with respect to whether an item or service that is subject to such a determination is an item or service to which the respective section applies. The Departments are of the view that it is important to ensure that consumers can avail themselves of external review in these situations and ensure that they are afforded full protection against surprise medical costs (including cost sharing), as intended by the No Surprises Act. Accordingly, these interim final rules amend the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review.

These interim final rules also amend the 2015 final regulations to add five new examples (examples number 3 through 7 in the regulation text) to clarify how the external review requirements apply to certain adverse benefit determinations involving items and services within the scope of the surprise billing and cost-sharing protections for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under section Code

section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2. The first new example illustrates that any determination of whether a claim is for treatment for emergency services that involves medical judgment or consideration of compliance with the cost-sharing and surprise billing protections is eligible for external review.

The second new example clarifies that whether a claim for items and services furnished by a nonparticipating provider at an in-network facility is subject to the protections under the No Surprises Act is eligible for external review because adjudication of the claim requires consideration of health care setting and level of care or compliance with cost-sharing and surprise billing protections.

The third new example clarifies that whether an individual was in a condition to receive a notice about the availability of the protections under the No Surprises Act and give informed consent to waive those protections is a claim eligible for external review because adjudication of the claim involves consideration of compliance with the cost-sharing and surprise billing protections and medical judgment.

The fourth new example illustrates that whether a claim for items and services is coded correctly, consistent with the treatment an individual actually received, is a claim eligible for external review because adjudication of the claim involves medical judgment.

The fifth new example illustrates that consideration of whether cost-sharing was appropriately calculated for claims for ancillary services provided by an out-of-network provider at an in-network facility involves consideration of compliance with the cost-sharing and surprise billing protections and is a claim eligible for external review.

The Departments solicit comment on these examples and whether any additional examples are needed. The Departments intend to ensure that this provision is implemented in a manner that affords consumers broad protection under section 110 of the No Surprises Act.

B. Application to Grandfathered Plans and Coverage

PHS Act section 2719 and its implementing regulations do not currently apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans because section 1251 of the Affordable Care Act provides that PHS Act section 2719 does not apply to grandfathered plans and coverage.

These interim final rules amend the regulations under PHS Act section 2719 to require grandfathered plans and coverage to provide for external review of claims covered by the protections of the No Surprises Act for plan years (or, in the individual market, policy years) beginning on or after January 1, 2022. This change is grounded in the text of section 110 of the No Surprises Act, in addition to the policy reasons stated earlier in this preamble regarding the Departments’ intent to implement this provision broadly. Section 110 states that external review requirements shall “apply with respect to any adverse determination by such a plan or issuer under section 2799A–1 or 2799A–2 of the PHS Act, section 716 or 717 of ERISA, or section 9816 or 9817 of the Code[.]” These sections of the PHS Act, ERISA, and the Code, as well as all the other provisions of the No Surprises Act, as discussed in section I.A of this preamble, are all applicable to grandfathered plans and coverage. Thus, to ensure that adverse benefit determinations under grandfathered plans and coverage for claims subject to those provisions are eligible for external review, external review requirements must be applicable to grandfathered plans and coverage for those claims. The Departments solicit comment on this amendment, including whether any additional guidance is warranted to help grandfathered plans and issuers comply with these requirements.

The Departments recognize that the internal claims and appeals rules under 29 CFR 2560.503–1, as incorporated under regulations implementing PHS Act section 2719,⁵⁸ do not apply to issuers offering grandfathered coverage in the individual market, or grandfathered non-Federal Government plans. Those grandfathered plans and issuers offering that grandfathered coverage must make external review available for adverse benefit determinations under PHS Act section 2799A–1 or 2799A–2 when an enrollee has exhausted applicable appeal rights under state law or under the terms of the enrollee’s coverage. In cases where these plans and issuers are not subject to a requirement to have an internal appeals process and have not otherwise instituted such a process, they must allow a claimant to request external review of an adverse benefit determination of claims covered by the protections under PHS Act sections 2799A–1 or 2799A–2 upon receipt of the adverse benefit determination.

⁵⁶ 76 FR 37207, 37216 (June 10, 2011).

⁵⁷ 80 FR 72191, 72209 (Nov. 18, 2015).

⁵⁸ 26 CFR 54.9815–2719; 29 CFR 2590.715–2719(c)(2)(i); 45 CFR 147.136.

V. Federal IDR Process for FEHB Carriers—Office of Personnel Management

OPM amends existing 5 CFR 890.114(a) to include references to the Departments' regulations to clarify that FEHB carriers are also subject to the Federal IDR process set forth in those regulations with respect to a qualified IDR item or service furnished by an FEHB carrier offering a health benefits plan in the same manner as those 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 FEHB carrier's contract. Through new paragraph 5 CFR 890.114(d), OPM adopts the Departments' rules as necessary to properly integrate the new standards with existing FEHB Program structure and sets forth the circumstances in which OPM will enforce these rules as applied to FEHB carriers, including by requiring carrier notice to the Director, in addition to the Departments, of an FEHB carrier's notice of initiation, or receipt of a provider's notice of initiation, the Federal IDR process. OPM will coordinate with the Departments in matters regarding FEHB carriers requiring resolution under the Federal IDR process and with respect to oversight of certified IDR entities' reports regarding FEHB carriers.

As discussed in the July 2021 interim final rules, all out-of-network rate determinations regarding qualified IDR items or services with respect to FEHB plans or carriers that are not resolved by open negotiation are subject to the Federal IDR process unless OPM contracts with FEHB carriers include terms that adopt state law as governing for this purpose.

VI. Overview of the Interim Final Rules Regarding Protections for the Uninsured—The Department of Health and Human Services

A. Good Faith Estimates for Uninsured (or Self-Pay) Individuals

1. Scope

The No Surprises Act adds PHS Act section 2799B–6(2), which requires health care providers and health care facilities, upon scheduling an item or service to be furnished to an individual or upon request of an individual, to inquire about such individual's health coverage status and to provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such item or service (including any item or service that is

reasonably expected to be provided in conjunction with such scheduled or requested item or service and such item or service reasonably expected to be so provided by another provider or facility), with the expected billing and diagnostic codes for any such item or service.

In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished, is not enrolled in a certain type of plan or coverage or is not seeking to file a claim with such type of plan or coverage, PHS Act section 2799B–6(2)(B), and these interim final rules at 45 CFR 149.610, require providers and facilities to furnish the good faith estimate to the individual. These requirements under 45 CFR 149.610 apply only to good faith estimate notifications for uninsured (or self-pay) individuals as described in 45 CFR 149.610(a)(2)(xii) of these interim final rules. As discussed in section I.C of this preamble, these interim final rules do not include requirements implementing PHS Act section 2799B–6(2)(A), which requires providers and facilities to furnish good faith estimates to individuals' plans or issuers.

2. Definitions

For purposes of 45 CFR 149.610, HHS is defining certain terms at 45 CFR 149.610(a). Specifically, "authorized representative" means an individual authorized under state law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with the facility or an employee of the facility represented in the good faith estimate, unless such provider or employee is a family member of the uninsured (or self-pay) individual. HHS considered defining authorized representative using the same definition as in 45 CFR 149.410 and 149.420; however, the definition in these interim final rules contain amendments to account for concepts that are not relevant to uninsured (or self-pay) individuals such as removing references to nonparticipating providers, participants, beneficiaries, and enrollees.

These interim final rules define, "convening health care provider or convening health care facility (convening provider or convening facility)" as the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service as defined in these interim final rules. As discussed

elsewhere in this preamble, the convening provider is responsible for providing the good faith estimate to an uninsured (or self-pay) individual.

HHS considered putting the responsibility for providing the good faith estimate on the "treating health care provider," as defined in 45 CFR 149.30, but for many scheduled items or services, multiple providers and facilities could participate in delivering an individual's care, or be considered, a "treating health care provider". Because it is likely that an individual would only schedule an item or service or request a good faith estimate from one of the treating providers or facilities, the convening provider or facility would likely need to request additional scheduling from other providers or facilities to participate in delivering care. Therefore, such a provider or facility would need to alert the other providers or facilities who are providing items or services in conjunction with the scheduled item or service, when items or services are scheduled or a good faith estimate is requested. Furthermore, HHS understands that multiple providers and facilities may bill an individual for the respective items or services provided during a period of care. Therefore, it is important to define who is responsible for furnishing the good faith estimate to the individual that is inclusive of all the items or services to be provided by co-providers and co-facilities involved in the scheduled items or services or the items or services for which a good faith estimate is requested.

In these interim final rules, "co-health care provider or co-health care facility (co-provider or co-facility)" means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service (as defined for purposes of this section). Because PHS Act section 2799B–6(2) requires that the good faith estimate include any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service (or such item or service for which a good faith estimate is requested) and such an item or service reasonably expected to be so provided by another health care provider or health care facility, HHS is distinguishing co-providers and co-facilities from the convening provider or convening facility who will furnish the good faith estimate inclusive of estimates from co-providers and co-facilities.

"Diagnosis code" means the code that describes an individual's disease,

disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set. In establishing requirements for implementation of HIPAA's Administrative Simplification provisions, HHS adopted specific code sets for diagnoses and procedures for use in standard health care transactions. The definition of diagnosis code used in this section aligns with the definition contained in the HIPAA Administrative Simplification standards at 45 CFR part 162.⁵⁹

For purposes of 45 CFR 149.610, "expected charge" means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

HHS understands that providers and facilities establish gross charges or chargemaster rates that are considered their standard charge for an item or services and then often discounts are applied depending on the payer (with the exception of state laws that specify payment rates). For instance, in providing a good faith estimate to a plan or issuer, the provider or facility may include as the expected charge the undiscounted gross charge or chargemaster rate, which would then be used by the plan or issuer to determine the out-of-pocket payment amount of an insured individual. HHS understands that providers and facilities often make adjustments to their gross charges or chargemaster rates to establish a self-pay rate for uninsured (or self-pay) individuals. HHS is of the view that if an individual is not enrolled in a plan or coverage or is enrolled but is not seeking to have a claim for such item or service submitted to their plan or coverage, the expected charges included in the good faith estimate should reflect what the provider or facility expects to bill or charge the payer (in this case the uninsured or self-pay individual), and therefore for the purpose of these interim final rules, HHS has defined expected charges specific to what the uninsured (or self-pay) individual would be expected to pay.

HHS is of the view that the estimate of expected charges must reflect the

anticipated billed charges, including any expected discounts or other relevant adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges because of the role of the good faith estimate in the patient-provider dispute resolution process under PHS Act section 2799B-7 and as specified in 45 CFR 149.620. Under PHS Act section 2799B-7, an uninsured (or self-pay) individual can seek a determination from an SDR entity if the total billed charge from a provider or facility is substantially in excess of the expected charges listed in the good faith estimate for the provider or facility. Therefore, as discussed in detail below, these interim final rules require that for each item or service listed in the good faith estimate, a provider or facility must include the expected charge for each item or service, reflecting any available discounts or other relevant adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges. For instance, certain hospital organizations that meet the general requirements for tax exemption under Code section 501(c)(3), are also required to meet the Financial Assistance Policy (FAP) requirements under Code sections 501(r)(4) through (6).⁶⁰ In this example, any adjustments expected to be applied under the FAP would be factored in and reflected in the amount reported in the good faith estimate for items or services. To promote more transparency, HHS considered requiring both undiscounted list prices and discounted prices to be included when discounted prices apply. HHS seeks comment on whether providers and facilities should be required to include both the list price and discounted price for an item or service when discounts apply.

Consistent with PHS Act section 2799B-6(2), these interim final rules define the term "good faith estimate" to mean a notification of expected charges for a scheduled or requested item or service,⁶¹ including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

"Health care facility (facility)" is defined more broadly than the

definition in 45 CFR 149.30, which applies in the context of balance billing protections for non-emergency services. For purposes of 45 CFR 149.610, "health care facility (facility)" means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any state in which state or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such state or locality responsible for licensing such institution as meeting the standards established for such licensing. While HHS considered applying the definition of health care facility from 45 CFR 149.30, doing so would limit the scope of providers and facilities for which 45 CFR 149.610 applies to only those providers relevant to the balance billing protections related to nonemergency items or services furnished by participating providers in nonparticipating facilities. The provisions in PHS Act section 2799B-6 do not specify such limitations.

For purposes of 45 CFR 149.610, "health care provider (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, including a provider of air ambulance services. As the Departments noted in the July 2021 interim final rules, the No Surprises Act does not define "provider." Some provisions use the word in a manner that includes providers of air ambulance services, while other provisions that use the word are inapplicable to providers of air ambulance services by the terms of the provisions. In this case, HHS is of the view that interpreting the term to include providers of air ambulance services in this context is critical to ensuring individuals obtain the benefits of a good faith estimate for a service that can be extremely costly. HHS recognizes that individuals will likely not be able to obtain a good faith estimate for emergency air ambulance services, as these are not generally scheduled in advance. However, making these requirements applicable to providers of air ambulance services helps to ensure that individuals can obtain a good faith estimate upon request or at the time of scheduling non-emergency air ambulance services, for which coverage often is not provided by a plan or issuer and thus even individuals with coverage often must self-pay.

⁶⁰ Financial Assistance Policy and Emergency Medical Care Policy. <https://www.irs.gov/charities-non-profits/financial-assistance-policy-and-emergency-medical-care-policy-section-501r4>.

⁶¹ For purposes of simplicity of language, these interim final rules in some instances refer to a requested good faith estimate for an item or service, as a requested item or service.

⁵⁹ <https://www.cms.gov/regulations-and-guidance/administrative-simplification/code-sets>.

“Items or services” has the same meaning given the term in 45 CFR 147.210(a)(2), which includes all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care. The definition of items or services in 45 CFR 147.210(a)(2) encompasses and accurately defines the types of items or services that are expected to be reported in the good faith estimate including items or services such as those related to dental health, vision, substance use disorders and mental health. HHS also clarifies that some items or services may not be included in a good faith estimate because they are not typically scheduled in advance and are not typically the subject of a requested good faith estimate, such as urgent, emergent trauma, or emergency items or services; however, HHS clarifies that to the extent an urgent care appointment is scheduled at least 3 days in advance, these interim final rules require a provider or facility to provide a good faith estimate.⁶²

These interim final rules also define the term “period of care” to mean the day or multiple days during which the good faith estimate for scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, and also includes the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished. HHS considered using the term episode of care but understands that the term episode of care is used within many different contexts regarding the provision of health care items or services.⁶³ In the context of this section, HHS is of the view that it is important to use the term period of care in order to clarify which items or services are expected to be provided in a good faith estimate.

“Primary item or service” means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit. HHS is of the view that additional

distinctions beyond the definition of “items or services” must be made in order for providers and facilities to furnish clear and understandable good faith estimates. HHS considered using the term “scheduled item or service” which would more directly align with the statutory language. However, such distinction would have excluded the statutory provision whereby a good faith estimate must be issued upon the request of an uninsured (or self-pay) individual when items or services have not been scheduled. HHS is of the view that using the term “primary item or service” provides clarity for providers and facilities to establish and identify a main item or service for which a good faith estimate is being issued. Based on the primary item or service, the provider or facility could subsequently identify and include all items or services that would be furnished in conjunction with the primary item or service, and such items or services reasonably expected to be provided by a co-provider or co-facility.

“Service code” means the code that identifies and describes an item or service using the CPT, HCPCS, DRG or National Drug Code (NDC) code sets. As noted earlier, in establishing requirements for implementation of HIPAA’s Administrative Simplification provisions, HHS adopted specific code sets for diagnoses and procedures for use in standard health care transactions. The definition of service code used in this section aligns with the definition contained in the HIPAA Administrative Simplification standards at 45 CFR part 162.⁶⁴

These interim final rules define the term “uninsured (or self-pay) individual” to mean an individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals, therefore these interim final rules include the term self-pay when

discussing uninsured individuals. As discussed elsewhere in this preamble, for the purposes of the interim final rules at 45 CFR 149.610 that implement PHS Act sections 2799B–6(1) and 2799B–6(2)(B), HHS is adopting the definition of uninsured (or self-pay) individuals from PHS Act sections 2799B–7 in order to align these two related sections.

HHS understands, and is of the view that it is appropriate, that consumers may request a good faith estimate without actually scheduling items or services to compare costs and make a decision about from which provider or facility they will seek care, or whether they will submit a claim to insurance or self-pay. These individuals would be considered self-pay for purposes of the requirement on the provider or facility to provide a good faith estimate. HHS clarifies that if an individual requests a good faith estimate as a self-pay individual and then ultimately decides to submit a claim to the individual’s plan or issuer for the billed charges, the individual is no longer considered a self-pay individual as defined in these interim final rules and would not be eligible to use the patient-provider dispute resolution process as defined in 45 CFR 149.620. HHS also clarifies that for purposes of 45 CFR 149.610 and 149.620, the definition of uninsured (or self-pay) individuals includes individuals enrolled in short-term, limited-duration insurance, as defined in regulations at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code.

HHS seeks comment on the terms defined in these interim final rules for purposes of this section. HHS is particularly interested in receiving information related to the appropriateness and usability of these definitions and whether additional terms should be included or defined.

3. Requirements for Providers and Facilities

For purposes of PHS Act sections 2799B–6, 2799B–6(1), and 2799B–6(2)(B) that are being implemented in these interim final rules, providers and facilities must meet certain requirements related to uninsured (or self-pay) individuals. Section 2799B–6 places the requirement to provide a good faith estimate, within the statutorily defined timeframes, upon

⁶² Certain urgent, emergent trauma, or emergency care services may be subject to other protections discussed in the July 2021 interim final rules (86 FR 36872).

⁶³ <https://www.healthaffairs.org/doi/10.1377/hblog20190326.202031/full/>.

⁶⁴ <https://www.cms.gov/regulations-and-guidance/administrative-simplification/code-sets>.

providers and facilities with whom an individual schedules an item or service, or from whom an individual requests a good faith estimate for an item or service, defined in these interim final rules as the convening provider or facility. However, HHS notes that section 2799B–6(2) requires that a good faith estimate of expected charges include any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service and such items or services reasonably expected to be so provided by another provider or facility, defined in these interim final rules as a co-provider or co-facility.

In order for good faith estimates to provide individuals with the most accurate information available, HHS is of the view that it is not feasible to fully implement the statutory provisions under PHS Act section 2799B–6(2) without establishing certain requirements for convening providers and facilities and co-providers and co-facilities. In implementing these provisions, HHS is of the view that to the extent possible, an uninsured (or self-pay) individual is entitled to receive a clear and understandable document that informs the uninsured (or self-pay) individual of the expected costs associated with the care that they are considering or are scheduled to receive, and in order to do so, the expected charges that inform the good faith estimate should be provided by all providers and facilities who are reasonably expected to furnish the items or services that would be billed to the uninsured (or self-pay) individual. HHS seeks comment on publicly available resources, methods, and potential standardized formatting or design that could facilitate communication of good faith estimate information in a clear and understandable manner.

To this end, HHS is of the view that issuance of separate good faith estimate documents from each provider and facility involved in furnishing care for a primary item or service would place undue administrative burden upon uninsured (or self-pay) individuals to then aggregate various good faith estimates received in order to obtain a clear and understandable representation of all expected charges for an item or service. However, HHS also acknowledges that in some instances, it would not be practical nor feasible to expect a convening provider or facility to have sufficient knowledge of the expected charges for each item or service provided by a co-provider or co-facility. HHS is also of the view that convening providers and facilities should not be held responsible for the

accuracy of expected charges for items or services for which the convening provider or facility does not bill the uninsured (or self-pay) individual (for instance, under the patient-provider dispute resolution process as described in 45 CFR 149.620).

HHS notes that the accuracy of the good faith estimate is relevant because if the actual billed charges substantially exceed the amounts reported in the good faith estimate, an uninsured (or self-pay) individual could seek a determination under the patient-provider dispute resolution process under 45 CFR 149.620. HHS is also of the view that it would not be appropriate to solely require that a convening provider or facility be accountable through the patient-provider dispute resolution process for items or services for which the convening provider or facility did not bill the uninsured (or self-pay) individual.

Therefore, HHS is using its general rulemaking authority to establish requirements under 45 CFR 149.610, discussed in detail below, for convening providers and facilities as well as co-providers and co-facilities for issuance of good faith estimates for uninsured (or self-pay) individuals. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary in order to implement the provisions of PHS Act section 2799B–6 in a manner that balances the statutory intent of providing uninsured (or self-pay) individuals with clear and understandable information regarding the expected costs of items or services, the responsibilities of various providers and facilities, and the inherent accountability established in the statute through the interaction between the issuance of good faith estimates under PHS Act section 2799B–6 and the patient-provider dispute resolution process under PHS Act section 2799B–7.

i. Requirements for Convening Providers and Facilities

These interim final rules establish in 45 CFR 149.610(b)(1) certain requirements for the convening provider or facility to verify whether an individual meets the definition of an uninsured (or self-pay) individual, to provide oral and written communication regarding the requirement to provide good faith estimates to uninsured (or self-pay) individuals upon scheduling an item or service or upon request, and to provide timely good faith estimates to uninsured (or self-pay) individuals. To determine whether a good faith estimate must be

provided to an individual under 45 CFR 149.610(b)(1), the convening provider or facility must inquire and determine if the individual meets the definition of an uninsured (or self-pay) individual as established in 45 CFR 149.610(a)(2).

HHS is of the view that conveying information about the availability of good faith estimates prior to or upon scheduling an item or service aligns with and is most relevant when uninsured (or self-pay) individuals are considering whether to proceed with medical care while interacting with their providers or facilities. Requiring that providers and facilities notify uninsured (or self-pay) individuals of the availability of good faith estimates will help ensure that all uninsured (or self-pay) individuals understand that they can request a good faith estimate and will also receive a good faith estimate upon scheduling an item or service and upon request.

Therefore, HHS is using its general rulemaking authority to establish in 45 CFR 149.610(b)(1)(iii) that the convening provider or facility must inform uninsured (or self-pay) individuals that good faith estimates of expected charges are available to uninsured (or self-pay) individuals upon scheduling an item or service or upon request. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be provided in writing and orally. The convening provider or facility must provide written notice in a clear and understandable manner prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur. In addition, the convening provider or facility must orally inform uninsured (or self-pay) individuals of the availability of a good faith estimate when questions about the cost of items or services occur. Information regarding the availability of a good faith estimate must be made available in accessible formats and languages spoken by individuals considering or scheduling items or services with such convening provider or convening facility.

HHS anticipates providing a model notice for notifying uninsured (or self-pay) individuals of the availability of good faith estimates. However, HHS is not requiring the use of such model notice in order to allow providers or facilities flexibility to develop notices that would be most effective for their patient populations. HHS also recognizes the potential value in having a standardized notice that uninsured (or

self-pay) individuals can anticipate across providers and facilities. Therefore, HHS seeks comment on the potential for standardizing notices for use by all convening providers and convening facilities and other alternative or concurrent options for informing uninsured (or self-pay) individuals of the availability of good faith estimates that would meet the requirements under this section.

HHS notes that uninsured (or self-pay) individuals may use different terminology other than “good faith estimate” when requesting a good faith estimate. Therefore, these interim final rules at 45 CFR 149.610(b)(1)(iv) specify that convening providers and convening facilities shall consider any discussion or inquiry regarding the potential cost of items or services under consideration as a request for a good faith estimate.

PHS Act section 2799B–6(2) requires that the good faith estimate include any item or service that is reasonably expected to be provided in conjunction with a scheduled or requested item or service by another provider or facility. Therefore, these interim final rules at 45 CFR 149.610(b)(1)(v) require that the convening provider or facility contact all applicable co-providers and co-facilities no later than 1 business day after the request for the good faith estimate is received or after the primary item or service is scheduled, and request submission of expected charges for items or services that meet the requirements for co-providers and co-facilities under 45 CFR 149.610(b)(2) and (c)(2). The convening provider or convening facility must indicate in their request the date that the good faith estimate information must be received from the co-provider or co-facility. The co-provider or co-facility is responsible for providing timely information to the convening provider or convening facility as discussed later in this preamble. HHS is of the view that the convening provider or convening facility would not have accurate estimates to include in the good faith estimate without information being provided in a timely manner by the co-provider or co-facility. HHS seeks comments on methods and standardized processes, including use of HIPAA standard transactions, that could facilitate accurate and efficient transmission of good faith estimate information from co-providers or co-facilities to convening providers or convening facilities.

PHS Act section 2799B–6 requires that providers and facilities furnish the good faith estimate of the expected charges within certain defined timeframes. Specifically, PHS Act

section 2799B–6 states that in the case of an individual who schedules an item or service to be furnished to such individual by such provider or facility at least 3 business days before the date such item or service is to be so furnished, that the notification of the good faith estimate of expected charges shall be provided no later than 1 business day after the date of such scheduling; in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the individual), that the notification of the good faith estimate of expected charges shall be provided no later than 3 business days after the date of such scheduling or such request. These interim final rules at 45 CFR 149.610(b)(1)(vi) codify these timeframes for good faith estimates.

HHS recognizes that circumstances may arise where the scope of information included in a good faith estimate changes (such as, a provider or facility represented in the good faith estimate is no longer able to furnish the items or services reported in the good faith estimate). In such circumstances, these interim final rules establish at 45 CFR 149.610(b)(1)(vii) and (viii) that the convening provider or convening facility must issue an uninsured (or self-pay) individual with a new good faith estimate no later than 1 business day before the item or service is scheduled to be furnished. If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement provider or replacement facility must accept the good faith estimate as their expected charges for the items or services being furnished that were provided by the original provider or facility and represented in the good faith estimate. These interim final rules also establish at 45 CFR 149.610(b)(2)(ii) and (iii) similar requirements for co-providers and co-facilities. HHS acknowledges the challenges these requirements impose on providers and facilities, and the potential disincentive that such a requirement could have on a provider’s or facility’s willingness to provide an item or service under such circumstances due to the fact that the patient-provider dispute resolution process, at 45 CFR 149.620, uses the good faith estimate to determine the eligibility of an item or service for dispute resolution. However, HHS is of the view that such requirements are necessary for consumer protections against facing surprise medical bills and

without such a requirement an uninsured (or self-pay) individual would be unable to avail themselves of the patient-provider dispute resolution process in these circumstances.

HHS expects that any replacement provider or facility considering whether to furnish items or services will review the applicable good faith estimate and use that information to determine whether to furnish the applicable items or services. HHS is of the view that requiring the replacement providers or facilities to accept as their good faith estimate the expected charges reported in the existing good faith estimate mitigates the risk of providers or facilities circumventing the requirements of PHS Act 2799B–6 through the substitution of providers or facilities. Such requirements also provide important consumer protections intended by PHS Act 2799B–6 that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills. However, HHS seeks comment on whether this approach could have unintended consequences, such as delays in care if providers were to refuse to serve as replacements, and ways in which to alleviate any such effects.

In instances where a good faith estimate is provided upon the request of an uninsured (or self-pay) individual, upon the subsequent scheduling of the item or service to be furnished, these interim final rules at 45 CFR 149.610(b)(1)(ix) establish that a new good faith estimate must be provided to the uninsured (or self-pay) individual for the now scheduled item or service, and within the timeframes specified for good faith estimates for scheduled items or services under 45 CFR 149(b)(1)(vi)(A) and (B). HHS recognizes that uninsured (or self-pay) individuals might choose to request a good faith estimate in order to better understand anticipated costs, for instance in situations where an individual may wish to compare costs across providers or facilities. If an uninsured (or self-pay) individual had not previously scheduled the primary item or service, the individual may not have been evaluated for underlying conditions that could impact the accuracy of the good faith estimate. HHS encourages convening providers or facilities to review any previously issued good faith estimate related to the primary item or service and make all applicable changes when providing the new good faith estimate. HHS also encourages convening providers or convening facilities to communicate these changes upon delivery of the new good faith estimate to help patients understand what has changed between the initial

good faith estimate and the new good faith estimate.

HHS acknowledges that there are circumstances where recurring items or services are expected to be furnished to an uninsured (or self-pay) individual (for example, an uninsured (or self-pay) individual may need multiple physical therapy visits that would occur outside of the period of care for a surgical procedure). These interim final rules establish at 45 CFR 149.610(b)(1)(x) that the convening provider or facility may issue a single good faith estimate for recurring primary items or services if certain requirements are met. The good faith estimate for recurring items or services must include in a clear and understandable manner the expected scope of the recurring items or services (such as: timeframes, frequency, and total number of recurring items or services) in the good faith estimate. The scope of such a good faith estimate must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months, a convening provider or convening facility must provide an uninsured (or self-pay) individual a new good faith estimate. Providers must also communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

ii. Requirements for Co-Providers and Co-Facilities

Under these interim final rules at 45 CFR 149.610(b)(2)(i), a co-provider or co-facility must submit, upon the request of the convening provider or convening facility, good faith estimate information for items or services that are reasonably expected to be furnished by the co-provider or co-facility in conjunction with the primary item or service (as specified under the content requirements discussed later in this section of the preamble). Good faith estimate information submitted by co-providers or co-facilities must be received by the convening provider or facility no later than 1 business day after the co-provider or co-facility receives the request. In addition, co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected

charges, items, services, frequency, recurrences, duration, providers, or facilities). If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

These interim final rules at 45 CFR 149.610(b)(2)(iv) also establish that in the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) for issuing a good faith estimate to an uninsured (or self-pay) individual.

4. Content of a Good Faith Estimate for an Uninsured (or Self-Pay) Individual

In 45 CFR 149.610(c), these interim final rules establish requirements for the content that must be included in a good faith estimate that is issued to an uninsured (or self-pay) individual. As discussed later in this section of the preamble, these interim final rules at 45 CFR 149.610(c)(1) establish the elements that must be included in the good faith estimate issued by the convening provider or convening facility and 45 CFR 149.610(c)(2) establishes the content requirements for good faith estimate information that must be submitted by co-providers or co-facilities to the requesting convening provider or convening facility.

Specifically, the good faith estimate issued by the convening provider or convening facility to the uninsured (or self-pay) individual must include:

- Patient name and date of birth;
- Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);
- Itemized list of items or services, grouped by each provider or facility, reasonably expected to be provided for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including: (1) Those items or services reasonably expected to be furnished by the convening provider or convening facility, and (2) those items

or services expected to be furnished by co-providers or co-facilities;

- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of each provider or facility represented in the good faith estimate, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;
- List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that states that separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services and that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;
- A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate of items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual of their right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in 45 CFR 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution

process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

Given that good faith estimate information submitted by co-providers or co-facilities must be included as part of the good faith estimate issued to the uninsured (or self-pay) individual, these interim final rules establish under 45 CFR 149.610(d)(2) that good faith estimate information submitted by co-providers or co-facilities to convening providers or convening facilities must include:

- Patient name and date of birth;
- An itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;
- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of the co-provider or co-facility, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and
- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

HHS expects that these requirements, along with the required methods and format for providing good faith estimates (see 45 CFR 149.610(e)) will result in good faith estimates that inform uninsured (or self-pay) individuals about the expected charges for the primary item or service, including the items or services reasonably expected to be furnished in conjunction with the primary item or service during a period of care.

The itemized list of items or services contained in a good faith estimate to an uninsured (or self-pay) individual must reflect the expected charges from the convening provider or facility and co-providers or co-facilities during a period of care. As discussed earlier, these interim final rules define a “period of care” as the day or multiple days during

which the good faith estimate for scheduled or requested items or services (or a set of items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider or convening facility or co-providers or co-facilities are furnishing such items or services, and also includes the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished. It is the intent of this definition of “period of care” to clarify that the good faith estimate should include all of the items or services that are typically scheduled as part of a primary item or service for which an individual does not need to engage in additional scheduling.

These interim final rules also establish at 45 CFR 149.610(c)(1)(vi) that in instances where a convening provider or convening facility anticipates that certain items or services will need to be separately scheduled (such as those items or services typical of the standard of care), the convening provider or facility must include a separate list of items or services that the convening provider or facility anticipates will require separate scheduling and that are expected to occur either prior to or following the expected period of care for the primary item or service. Additionally, the good faith estimate must include a disclaimer directly above this list that notifies the uninsured (or self-pay) individual that: (1) Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling of the listed items or services or upon request; and (2) for items or services included in this list, information such as diagnosis codes, service codes, expected charges, and provider or facility identifiers may not be included as that information will be provided in separate good faith estimates upon scheduling of such items or services or upon request; and (3) include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services.

HHS also considered requiring that the good faith estimate include contact information for a provider’s or facility’s financial assistance office. HHS seeks comment on whether or not such information should be required on the good faith estimate.

HHS understands the value in having one good faith estimate that includes all items or services furnished prior to, as part of, and following the primary item

or service, regardless of whether the items or services must be separately scheduled. HHS also understands that including all this information in one good faith estimate could potentially be helpful in allowing an uninsured (or self-pay) individual to fully understand their anticipated costs. However, HHS also appreciates the complexity in obtaining such information by a convening provider or convening facility, as the convening provider or convening facility may not be privy to or be able to reasonably predict which additional providers or facilities an uninsured (or self-pay) individual may choose to engage with outside of the period of care for the primary item or service. HHS seeks comment on whether the good faith estimate content should be expanded to include additional information and expected charges for items or services that are anticipated to be furnished prior to or following the period of care for the primary item or service but require separate scheduling by the uninsured (or self-pay) individual. HHS is particularly interested in the benefits, challenges, and resources that could facilitate provision of good faith estimates that include items or services beyond the period of care for the scheduled or requested primary items or services.

HHS provides the following example for illustrative purposes only and notes that this example should not be considered or construed to be comprehensive or applicable to any specific individual or set of circumstances. In the instance of a knee surgery, a good faith estimate could include an itemized list of items or services in conjunction with and including the actual knee surgery (such as physician professional fees, assistant surgeon professional fees, anesthesiologist professional fees, facility fees, prescription drugs, and durable medical equipment fees) that occur during the period of care. An individual would not typically schedule days in the hospital post-procedure separately from scheduling the primary service of a knee surgery. HHS would therefore expect that all the items or services that are reasonably expected to be provided from admission through discharge as part of that scheduled knee surgery, from all physicians, facilities, or providers be included in the good faith estimate.

Additionally, in this illustrative example, a provider or facility would furnish separate good faith estimates upon scheduling or upon request for any items or services that are necessary prior to or following provision of the

primary item or service beyond the period of care. Examples could include certain pre-operative or post-operative items or services that are not typically scheduled during the period of care for the knee surgery, such as certain laboratory tests or post-discharge physical therapy as discussed earlier.

HHS acknowledges that unforeseen factors could occur during the course of treatment, which could involve additional services, resulting in higher actual billed charges after receipt of care than was anticipated at the time the good faith estimate was provided to the uninsured (or self-pay) individual. These interim final rules do not require the good faith estimate to include charges for unanticipated items or services that are not reasonably expected and that could occur due to unforeseen events.

HHS expects that providers and facilities will use the coding that best describes the item or service for each item or service listed in the good faith estimate. When a single service code is available that captures reporting and billing for the component parts of an item or service, the single service code and expected charge for that single service code would be reported in the good faith estimate to capture the most comprehensive coding level; the component parts would not be included in the good faith estimate as they would not be separately reported or billed. For example, CPT code 85027 (*complete (CBC), automated (Hgb, Hct, RBC, WBC*

and platelet count)) represents a laboratory test that measures a patient's hematocrit, hemoglobin, red blood cell count, leukocyte (white blood cell) counts, and platelet count. There are also individual CPT codes for each of the component parts of the service represented by CPT code 85027 (CPT codes: 85014 (*hematocrit (Hct)*), 85018 (*hemoglobin (Hgb)*), 85041 (*red blood cell (RBC), automated*), 85048 (*leukocyte (WBC), automated*), and 85049 (*platelet, automated*)). However, HHS expects that the good faith estimate would include expected charges for CPT code 85027, not expected charges for each component part since there is a single CPT code available that better captures reporting for all of the component parts of the laboratory service.⁶⁵

Items or services included in the good faith estimate must be itemized (by each applicable service code), and clearly grouped and displayed as corresponding to the respective provider or facility that is expected to furnish those items or services. For each provider or facility represented in the good faith estimate, the total amount of expected charges must be included and displayed. HHS is of the view that certain identifying information (such as the provider's or facility's NPI and TIN) must be included in the good faith estimate to ensure that each provider or facility is accurately identified, particularly in instances where more than one provider or facility have the same name, but are separate

and distinct entities for purposes of billing for items or services.

Chart 1 provides a visual example of how itemized lists of expected items or services could be displayed in the good faith estimate as suggested in the HHS model notice. HHS notes that this example is included for demonstration purposes only, is not required, and is not a mandatory or standardized format. HHS seeks comment on options for displaying and methods for standardizing the formatting for the itemized lists of items or services, and the required disclaimers. HHS also seeks comment regarding the potential benefits and challenges of using a standardized form that could serve as a base for good faith estimates issued to uninsured (or self-pay) individuals. As uninsured (or self-pay) individuals may be unfamiliar with reading and understanding itemized lists of items or services typically charged for by providers or facilities, HHS seeks comment regarding whether the notice should be required to include additional information to explain concepts such as itemized lists of items or services, content within the required disclaimers, or other information included within the good faith estimate. HHS is also interested in information regarding publicly available methods for displaying required information in good faith estimates in a clear and understandable manner.

CHART 1—EXAMPLE OF HOW ITEMIZED LISTS OF EXPECTED ITEMS OR SERVICES COULD BE DISPLAYED IN A GOOD FAITH ESTIMATE FOR UNINSURED (OR SELF-PAY) INDIVIDUALS
DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 1]

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number].
Total Expected Charges from [Provider/Facility 1]				\$

Additional Health Care Provider/Facility Notes

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 2]

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number].

⁶⁵ CPT codes and descriptions are copyright 2020 American Medical Association. All Rights

Reserved. CPT is a registered trademark of the American Medical Association (AMA).

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 2]—Continued

Service/item	Address where service/item will be provided	Diagnosis code	Service code	Quantity	Expected cost
Total Expected Charges from [Provider/Facility 1]				\$

Additional Health Care Provider/Facility Notes

5. Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals

In 45 CFR 149.610(e), these interim final rules establish required methods for providing good faith estimates to uninsured (or self-pay) individuals. Consistent with statutory requirements, these interim final rules establish at 45 CFR 149.610(e)(1) that the good faith estimate must be provided in written form either on paper or electronically (for example, electronic transmission of the good faith estimate through the convening provider’s patient portal or electronic mail), pursuant to the uninsured (or self-pay) individual’s requested method of delivery, and within the timeframes specified under 45 CFR 149.610(b). For good faith estimates provided electronically, the good faith estimate must be provided in a manner that the uninsured (or self-pay) individual can both save and print, and must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.⁶⁶

HHS notes that the good faith estimate is necessary for initiating the patient-provider dispute resolution process under 45 CFR 149.620, and thus must be issued in written form. Additionally, 45 CFR 149.610(e)(2) of these interim final rules establishes that to the extent that an uninsured (or self-pay) individual requests a good faith estimate be provided other than by paper or electronically (for example, by phone or orally in person), the convening provider or facility may orally discuss the information included in the good faith estimate. However, in order to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate in written form. The good faith estimate may be provided to an uninsured (or self-pay) individual’s authorized representative instead of the individual, to the extent not prohibited under state law. HHS notes that

authorized representatives from state Consumer Assistance Programs (CAPs) or legal aid organizations may also be resources for assisting individuals with good faith estimates. HHS recognizes and notes that similar discussions related to authorized representatives (and communication needs of underserved populations discussed elsewhere in this preamble) were also discussed in the July interim final rules. These interim final rules adopt similar standards for authorized representatives as the July 2021 interim final rules, with amendments to account for concepts that are not relevant to uninsured (or self-pay) individuals such as removing references to nonparticipating providers, participants, beneficiaries and enrollees.

In interpreting the statutory requirements regarding the use of clear and understandable language, HHS recognizes that communication, language, and literacy barriers are associated with decreased quality of care, poorer health outcomes, and increased utilization.⁶⁷ The use of appropriate language services and 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.⁶⁸ HHS is of the view that it is imperative that providers and facilities make these efforts to provide good faith estimate information in a manner understandable to the uninsured (or self-pay) individual to help achieve the goal of the statute and ensure that uninsured (or self-pay) individuals are aware of the good faith estimate information and the options available to them. HHS is of the view that when providing a good faith estimate, providers or facilities should also take into account any vision, hearing, or language limitations; communication needs of underserved populations; individuals with limited English proficiency; and persons with health literacy needs. These factors meaningfully contribute to whether the

uninsured (or self-pay) individual can understand and ask any questions about the total expected costs for items or services.

Providers and facilities are also required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds providers and facilities that are recipients of Federal financial assistance that they must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act,⁶⁹ Title VI of the Civil Rights Act of 1964,⁷⁰ and Section 504 of the Rehabilitation Act of 1973.⁷¹ 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 providing qualified interpreters, written or sight translation of written good faith estimates in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. 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 in a timely manner and free of charge to the individual. Auxiliary aids and services may include sign language 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.

HHS seeks comment from persons in and representatives of racial/ethnic

⁶⁶ For additional resources, see Federal Plain Language Guidelines at <https://www.plainlanguage.gov/guidelines/>.

⁶⁷ Flores G. Language barriers to health care in the United States. *N Engl J Med* 2006; 355:229–231.

⁶⁸ *Id.*

⁶⁹ 42 U.S.C. 18116.

⁷⁰ 42 U.S.C. 2000d *et seq.*

⁷¹ 29 U.S.C. 794.

minority and underserved communities, including those with limited English proficiency and those with disabilities who require information in alternate and accessible formats, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, 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 good faith estimates. HHS also seeks comment on how to best provide additional help and resources for these individuals, including state CAPs, legal services or other aid that may help patients with good faith estimates. HHS also seeks comment on additional or alternate policies HHS may consider to help address and remove such barriers. In furtherance of the goal of reducing disparities in health care and coverage, HHS intends to analyze data related to individuals' use of the patient-provider dispute resolution process described under 45 CFR 149.620, as added by PHS Act section 2799B-7, and the appeals process described under 45 CFR 147.136, as added by PHS Act section 2719, to understand where barriers to coverage or accessible information persist. HHS is seeking comment on how to use data related to these two processes to understand, analyze, and address continued disparities.

HHS is seeking comment on how the required methods for providing a good faith estimate to uninsured (or self-pay) individuals established under 45 CFR 149.610 may affect small or rural providers or facilities. HHS is particularly interested in whether there are alternatives to these interim policies that HHS could consider for potential future rulemaking that could meet the statutory requirements for provision of good faith estimates to uninsured (or self-pay) individuals.

6. Additional Compliance Provisions

HHS is of the view that compliance provisions (established at 45 CFR 149.610(f) of these interim final rules) are necessary to ensure that providers and facilities have taken reasonable steps to ensure the accuracy of the information included in a good faith estimate. These interim final rules further clarify in 45 CFR 149.610(e)(1) that a good faith estimate issued to an uninsured (or self-pay) individual is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record, and that convening providers and facilities must provide a copy of

any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

While HHS acknowledges that some states have existing state laws related to the furnishing of good faith estimates, HHS is of the view that uninsured (or self-pay) individuals should still have access to a good faith estimate that meets the minimum requirements established in these interim final rules. Therefore at 45 CFR 149.610(f)(2) these interim final rules establish that providers or facilities that issue good faith estimates under state processes that do not meet the minimum requirements under this section fail to comply with the requirements of 45 CFR 149.610.

In circumstances in which a provider or facility, acting in good faith, makes an error or omission in a good faith estimate, HHS is establishing at 45 CFR 149.610(f)(3) that a provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. However, if the services are furnished before the error in the good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the billed charges are substantially in excess of the good faith estimate (as described in 45 CFR 149.620).

Additionally, to the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, these interim final rules specify at 45 CFR 149.610(f)(4) that the provider or facility will not fail to comply with this section because it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. HHS notes that providers and facilities (including convening providers, convening facilities, co-providers or co-facilities) who experience other providers' or facilities' failures to comply with the requirements in these interim final rules may file a complaint for enforcement investigation under 45 CFR 149.450. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable,

and as noted above, may be subject to patient-provider dispute resolution if items or services furnished before a corrected good faith estimate could be issued to an uninsured (or self-pay) individual.

7. Applicability of the Good Faith Estimate Requirements

These interim final rules establish under 45 CFR 149.610(g)(1) that the requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 by uninsured (or self-pay) individuals or for good faith estimates required to be provided to uninsured (or self-pay) individuals in connection with items or services scheduled on or after January 1, 2022. HHS recognizes that some providers or facilities may need to establish efficient and secure communication channels for transmission of good faith estimate information between convening providers or facilities and co-providers and co-facilities. While HHS notes that there are longstanding established standards for data exchange between providers established under HIPAA,⁷² HHS is seeking comment on any existing challenges related to secure transmission of good faith estimate information between providers and facilities. HHS is also interested in whether publicly available standardized processes exist or could be developed that would facilitate and support efficient and timely transmission of good faith estimate information. HHS also seeks comments on how the Hospital Price Transparency requirements for hospitals to display standard charges in a consumer-friendly manner (45 CFR 180.60), and, specifically, the voluntary use of online price estimator tools (45 CFR 180.60(a)(2)), may be leveraged to provide a good faith estimate under these final rules. HHS also seeks comments on whether there are other opportunities for the convening provider to use the Hospital Price Transparency machine-readable file requirements (45 CFR 180.50) to inform good faith estimates with expected charges of co-providers or co-facilities from the comprehensive machine-readable files, whether or not the comprehensive machine-readable files can assist uninsured (or self-pay) individuals in determining if the good faith estimate charges are reasonable and/or accurate, and what limitations exist in using the comprehensive machine-readable files for purposes of

⁷² <https://www.cms.gov/regulations-and-guidance/administrative-simplification/hipaa-aca>.

meeting the requirements of this section for provision of the good faith estimates to uninsured (or self-pay) individuals. General information regarding relevant interoperability or data exchange standards would also be of interest.

These interim final rules at 45 CFR 149.610(g)(2) establish that nothing in 45 CFR 149.610 alters or otherwise affects a provider's or facility's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the extent a state law prevents the application of this section.

HHS understands that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information from co-providers and co-facilities. Therefore, for good faith estimates provided to uninsured (or self-pay) individuals from January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where a good faith estimate provided to an uninsured (or self-pay) individual does not include expected charges from co-providers or co-facilities. HHS notes that nothing prohibits a co-provider or co-facility from furnishing the information before December 31, 2022, and nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or co-facility, in which case the co-provider and co-facility would be required to provide the good faith estimate for such items or services. Otherwise during this period, HHS encourages convening providers and convening facilities to include a range of expected charges for items or services reasonably expected to be provided and billed by co-providers and co-facilities. To the extent states are the primary enforcer of these requirements, HHS encourages states to take a similar approach, and will not consider a state to be failing to substantially enforce these requirements if it takes such an approach from January 1, 2022 through December 31, 2022.

8. Applicability of Requirements to Notices Provided Under 45 CFR 149.420

The July 2021 interim final rules included provisions at 45 CFR 149.420(d) establishing the information that must be included in a written notice, if a non-participating provider or

non-participating emergency facility seeks to obtain consent from a participant, beneficiary, or enrollee (or their authorized representative) to waive the balance bill protections. Specifically, the written notice must be provided in a form and manner specified by HHS in guidance, and must, among other things, 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). In the July 2021 interim final rules, HHS stated that in calculating the good faith estimated amount required to be included in the notice under 45 CFR 149.420(d)(2), the provider or facility is expected to apply the same process and considerations used to calculate the good faith estimate that is required under PHS Act section 2799B-6(2).

HHS recognizes that providers and facilities have some discretion in the assumptions that they make regarding which items or services to include in a good faith estimate, and that some natural variation may occur across providers and facilities in terms of which items or services they would include in an estimate. However, HHS is of the view that it is critical for providers and facilities to apply the same process and considerations in developing the good faith estimate required under PHS Act section 2799B-6(2) (as partially implemented in these interim final rules at 45 CFR 149.610) as in 45 CFR 149.420(d)(2) to avoid consumers receiving two different estimates describing care from the same provider or facility for the same care.⁷³

Under 45 CFR 149.610, the "expected charge" for an item or service may vary depending on whether the good faith estimate is being provided to an uninsured (or self-pay) individual, or to a plan or issuer. HHS clarifies that the good faith estimate in the notice described in 45 CFR 149.420(c) must be developed using the definition of the expected charge that would apply when

⁷³ For individuals who are seeking to submit a claim to their plan or coverage, the second estimate would be sent to the plan or issuer and used to develop the advanced explanation of benefits required to be provided under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A-1(f). As discussed previously, the Departments will defer enforcement of these requirements until the Departments have issued rulemaking regarding the requirements. The Departments recognize that participants, beneficiaries, and enrollees would not receive a second estimate (in the advanced explanation of benefits) from their plan or issuer until this rulemaking goes into effect.

the good faith estimate is provided to a plan or issuer (that is, the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service). Because the notice in 45 CFR 149.420(c) would only be provided with respect to individuals enrolled in a group health plan or health insurance coverage, HHS is of the view that requiring the good faith estimate to align with the good faith estimate that would be provided under PHS Act section 2799B-6(2)(A) to a plan or issuer will help to avoid situations in which participants, beneficiaries, or enrollees subsequently receive an advanced explanation of benefits from their plan or issuer that is generated from a different estimate than the one provided in the notice, or in which participants, beneficiaries, or enrollees receive differing estimates regarding notice and consent under 45 CFR 149.420(d)(2) and regarding self-pay liability under 45 CFR 149.610. In instances where an individual receives a notice with a good faith estimate reflecting the amount that would be billed to a plan or issuer but intends to self-pay and the item or service is scheduled in advance, the individual would separately receive a good faith estimate reflecting the amount they would be charged as a self-pay individual under the requirements in 45 CFR 149.610. HHS acknowledges that the Departments are not codifying requirements regarding PHS Act section 2799B-6(2)(A), which requires providers and facilities to furnish good faith estimates to plans or issuers, and that HHS will defer enforcement of this requirement until rulemaking is effective to fully implement this requirement. That non-enforcement position does not extend to the requirement to provide a good faith estimate as part of the notice under 45 CFR 149.420(c). However, HHS seeks comment on whether providers and facilities should be allowed to calculate the good faith estimate under 45 CFR 149.420(d)(2) using the expected charge applicable to an uninsured (or self-pay) individual until such rulemaking occurs. HHS also seeks comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request during this period of non-enforcement.

HHS recognizes that the good faith estimates required under 45 CFR 149.420(d)(2) and 45 CFR 149.610 may also differ if items or services from different provider(s) or facilities are included in the estimate. For example,

an estimate required in the notice under 45 CFR 149.420(d)(2) would only include items or services provided by a nonparticipating provider that seeks to obtain consent to balance bill. In contrast, the good faith estimate required under these interim final rules would not be limited to items or services furnished by such providers. However, HHS expects that the estimates regarding items or services provided by a specific provider or facility in the notice provided under 45 CFR 149.420(c) would include the same items or services for that specific provider or facility as the good faith estimate provided under 45 CFR 149.610. Although the grand total of a good faith estimate under each of the two rules might differ depending on the number of providers furnishing estimates as part of one good faith estimate, HHS is of the view that the requirements in each of the two rules generally take into account the same process and considerations for calculating the good faith estimate.

B. Patient-Provider Dispute Resolution

1. Scope

PHS Act section 2799B–7 directs the Secretary of HHS to establish a process called a patient-provider dispute resolution process. Under this process an uninsured (or self-pay) individual who received a good faith estimate of the expected charges for an item or service, pursuant to PHS Act section 2799B–6, implemented at 45 CFR 149.610, may seek a determination from an SDR entity for the amount to be paid by the uninsured (or self-pay) individual to the provider or facility for such item or service. Uninsured (or self-pay) individuals are eligible for the patient-provider dispute resolution process after being furnished an item or service for which they received a good faith estimate if the individual is billed, by the provider or facility, charges that are substantially in excess of the good faith estimate.

HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process. These interim final rules include specific definitions related to the patient-provider dispute resolution process; specify the items and services eligible for the process; establish requirements for what uninsured (or self-pay) individuals must provide to initiate the process; and specify the information providers and facilities must provide to an SDR entity to inform payment determinations. These interim final rules also establish requirements for SDR entities contracted to resolve the

patient-provider dispute, including how SDR entities determine the payment amount, and certification standards that HHS will consider when contracting with SDR entities. These interim final rules also specify the administrative fee associated with the patient-provider dispute resolution process, and the minimum requirements for state patient-provider dispute resolution processes to operate in place of the Federal patient-provider dispute resolution process.

2. Definitions

For purposes of these interim final rules, the definitions under 45 CFR 149.610 apply. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach, individually identifiable health information (IIHI)*, and *unsecured IIHI* also apply to this section. These interim final rules also define three additional terms: “billed charge,” “substantially in excess,” and “total billed charges” under new 45 CFR 149.620(a)(2).

These interim final rules define “billed charge” to mean the amount billed by a provider or facility for an item or service. These interim final rules define “total billed charges” to mean the total of billed charges, by a provider or facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

These interim final rules define the term “substantially in excess” to mean with respect to the total billed charges by a provider or facility, an amount that is at least \$400 more than the total amount of expected charges for the provider or facility listed on the good faith estimate. In defining “substantially in excess,” HHS notes that PHS Act section 2799B–7 does not include a definition for “substantially in excess.” HHS reviewed other uses of the term in existing Federal law. For example, section 1128(b)(6) of the Social Security Act provides that the Secretary of HHS may exclude any individual or entity from participation in any Federal health care program if the Secretary determines that the individual or entity submitted bills or requests for payment (where such bills or requests are based on charges or cost) under title XVIII of the Social Security Act or a state health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual’s or entity’s usual charges (or, in applicable cases, substantially in

excess of such individual’s or entity’s costs) unless the Secretary finds there is good cause for such bills or requests containing such charges or costs. However, HHS notes that section 1128(b)(6) of the Social Security Act similarly does not include a definition for “substantially in excess.” Regardless, HHS is of the view that the term “substantially in excess” as used in PHS Act section 2799B–7 should be distinguished from the language of section 1128(b)(6) of the Social Security Act, as the provisions operate differently. Specifically, PHS Act section 2799B–7 specifies that an uninsured (self-pay) individual is eligible to seek a payment determination regarding the amount to be paid when the total billed charges substantially exceed the total expected charges in the good faith estimate. HHS is of the view that such a process should provide clear criteria that would make it easy for uninsured (or self-pay) individuals, providers, facilities, SDR entities, and HHS to determine eligibility for dispute resolution. HHS is also of the view that such eligibility criteria should be based on objective factors that are known in advance and are simple for providers, facilities, and uninsured (or self-pay) individuals to understand, which will reduce uncertainty over which items or services are subject to dispute resolution and which are not.

HHS considered establishing a definition for “substantially in excess” to mean that the total billed charges are greater than the total expected charges in the good faith estimate by a percentage of the total expected charges in the good faith estimate (for example, 20 percent of the total expected charges). However, HHS is mindful of the limitations in relying on percentages for determining the threshold of eligibility for dispute resolution. In particular, when using percentages, the dollar thresholds would vary significantly based on the magnitude of the expected charges in the good faith estimate. For example, if for an item or service, the expected charge in the good faith estimate is \$300, 20 percent would equal \$60, meaning the billed charges would need to equal or exceed \$360 to be eligible for dispute resolution. However, if for an item or service, the expected charge in the good faith estimate is \$25,000, the difference between the billed charge and the expected charge in the good faith estimate would need to be \$5,000 or greater to be eligible for dispute resolution. In other words, basing the definition of “substantially in excess” on a percentage of the total expected

charges in the good faith estimate would make dispute resolution easier to access in cases where the associated dollar amounts are small. Conversely, in cases where the associated dollar amounts are very large, the threshold would be significantly larger in terms of dollars and more difficult for the claims to meet, which could result in many uninsured (or self-pay) individuals being unable to access dispute resolution despite receiving bills for items or services in amounts far greater, in absolute value, than the expected charges in the good faith estimate.

To address these limitations, HHS considered alternative approaches that included defining “substantially in excess” to mean that the total billed charges are greater than the total expected charges in the good faith estimate by the lesser of a percentage of the total expected charges in the good faith estimate or a flat maximum dollar amount. While this approach would mitigate concerns over higher cost items and services meeting the “substantially in excess” threshold, it would not address concerns over the uninsured (or self-pay) individual being easily able to bring dispute resolution claims for lower cost items or services. HHS is concerned that under such an approach, dispute resolution for lower cost items or services could be overused, thus potentially increasing costs for providers and facilities which could be passed on to individual consumers in the form of higher prices.

Similarly, HHS considered defining “substantially in excess” to mean an amount that is the greater of either a percentage of the total expected charges in the good faith estimate or a flat minimum dollar amount. By specifying a flat minimum dollar threshold amount, such an approach would address concerns over overuse of the patient-provider dispute resolution process for items or services at the lower end of costs. However, HHS remains concerned that such an approach could effectively put dispute resolution out of reach for uninsured (or self-pay) individuals in situations where the total expected charges for items or services are high, particularly for those who need to undergo more complex procedures. As an example, under this approach, when the total billed charges must be either equal to or greater than a flat minimum amount or predefined percentage above the expected charges, if the applicable flat amount is \$400 and the applicable percentage of the expected charges in the good faith estimate were equal to 10 percent, total expected charges of \$25,000 would mean the total billed charges must

exceed the total expected charges in the good faith estimate by \$2,500 or more in order to access dispute resolution. If, in this example, the total billed charges are less than \$27,500, the uninsured (or self-pay) individual would be unable to resolve the unexpected bill using the patient-provider dispute resolution process. Even for individuals with sufficient savings or income, such a threshold would likely pose a major financial burden, and such a situation would be exacerbated for lower income individuals and those who lack sufficient savings. HHS is of the view that whether an individual needs to receive a high cost item or service is independent from an individual’s income or assets or coverage status, and basing the definition of “substantially in excess” for the purposes of eligibility for the patient-provider dispute resolution process on the expected charges of an item or service without any consideration for the financial means of the uninsured (or self-pay) individual would create a massive gap in the consumer protections intended under PHS Act section 2799B–7. To provide another example, suppose an uninsured (or self-pay) individual has total expected charges in the good faith estimate equal to \$2,100 and the “substantially in excess” standard is the greater of 10% of the total expected charges in the good faith estimate or \$400. Under such a definition, the substantially in excess threshold would be \$400, and if the total billed charges are \$2,500 or greater, then the items or services are eligible for dispute resolution. Now, consider another uninsured (or self-pay) individual with total expected charges of \$21,000; in this uninsured (or self-pay) individual’s case, the total billed charges would need to exceed the total expected charges in the good faith estimate by \$2,100 or more in order to be eligible for dispute resolution. The uninsured (or self-pay) individual with expected charges of \$21,000 is in no less need of protection from surprise medical bills than the uninsured (or self-pay) individual with expected charges of \$2,100, but in practice such individual would more likely be unable to access these important protections intended by the patient-provider dispute resolution due to the higher threshold.

HHS also considered a tiered percentage approach in which lower-cost services must exceed a higher percentage value, with a lower percentage value applicable for higher-cost items or services. However, HHS is of the view that such an approach would add undue complexity to the

patient-provider dispute resolution process in determining whether items or services meet the “substantially in excess” threshold and would present the same concerns previously described. HHS also considered basing the definition of “substantially in excess” on billed charges that exceed a certain percentile for the same or similar services using an independent database. However, such a mechanism appears inconsistent with the statute, which contemplates costs for items or services to be determined “substantially in excess” based on the good faith estimate provided, rather than based on a specific benchmark, such as an independent database.

HHS is of the view that basing the definition of “substantially in excess” on a flat dollar amount, such as \$400, allows for a straightforward way to calculate the eligibility of an item or service for patient-provider dispute resolution, and reduces the concerns described earlier regarding lower-cost items or services too easily meeting the eligibility threshold for dispute resolution and making it more difficult for higher-cost items and services to meet the eligibility threshold. HHS acknowledges that such an approach may result in situations in which the difference between the total billed charges and the total expected charges in the good faith estimate is small in relative terms but the item or service is eligible for dispute resolution. As an example, if the expected charge for an item or service in the good faith estimate is \$100,000, basing “substantially in excess” on a flat \$400 threshold, a billed charge of \$100,400 (0.4% difference) or more would make the item or service eligible for dispute resolution, which could be argued by some as not “substantially in excess.” However, as discussed earlier in this section of the preamble, HHS is of the view that while the definition of “substantially in excess” should encompass the difference between the total billed charges and the total expected charges in the good faith estimate, focusing solely on the expected costs of items or services risks shutting out many uninsured (or self-pay) individuals from the patient-provider dispute resolution process and undermines the intended protections in PHS Act section 2799B–7. Additionally, even when the total expected charges are high, a relatively small additional charge may still create significant financial difficulties for the uninsured (or self-pay) individual. HHS did consider whether to have different flat dollar thresholds based on the

uninsured (or self-pay) individual's income, however, HHS is of the view that such a policy would be confusing to uninsured (or self-pay) individuals who would need to provide documentation to verify their income, which increases the burdens placed on such individuals and could pose a deterrent to participation. Based on consideration of the different approaches discussed earlier in this section of the preamble, HHS determined that the best approach for defining "substantially in excess" would be to base it on a flat dollar difference between the total billed charges and the total expected charges in the good faith estimate.

Because HHS views the patient-provider dispute resolution process established under PHS Act section 2799B-7 to be intended to protect uninsured (or self-pay) individuals from unexpected higher health care costs, it is appropriate to determine whether an amount is substantially in excess based on the perspective of individuals who are likely to be uninsured or underinsured, and not only the perspective of the average individual or the provider or facility. To that end, HHS looked to existing research to assess what amount Americans may struggle to cover in unexpected expenses. HHS is of the view that looking to Americans' ability to cover unexpected expenses is an important consideration when establishing protections for unexpected medical expenses, which remain a common unexpected expense for many. In a 2016 survey, the Federal Reserve reported that 22 percent of respondents experienced what they described as a major unexpected medical expense that they had to pay out-of-pocket in the previous 12 months.⁷⁴ Further, concerns over the potential costs of medical care may result in many Americans choosing to forego needed care.⁷⁵ Another recent study found that in 2020, 17.8 percent of individuals had medical debt reported to a credit bureau, the study

also found that individuals collectively had greater medical debt in collections than all forms of nonmedical debt combined (the authors defined nonmedical debt as other sources of debt in collections, including credit cards, personal loans, utilities, and phone bills).⁷⁶

In 2019, the Federal Reserve found that nearly 4 in 10 adults would have difficulty covering an emergency expense costing \$400, with 12 percent of adults unable to pay their current month's bills if they also had an unexpected \$400 expense.⁷⁷ The ability to cover an unexpected expense also varies significantly by social risk and demographic factors, for example, income, race, perceived health, and depression.⁷⁸ A 2016 survey by the Federal Reserve found that among respondents with a family income under \$40,000, only 34 percent reported they would be able to pay an unexpected \$400 expense using cash or its functional equivalent (including money currently in their checking/savings accounts, or available on a credit card that they would pay in full at their next statement). In addition, the Federal Reserve found that while 61 percent of non-Hispanic white respondents said that they would pay for an unexpected \$400 expense using cash or its functional equivalent, for Hispanic and non-Hispanic black respondents, only 38 percent and 36 percent respectively reported that they would be able to pay for an unexpected \$400 expense using cash or its functional equivalent.⁷⁹

Other surveys have found results that were consistent with the Federal Reserve's findings. One such survey found that only 39 percent of Americans would cover an unexpected \$1,000 expense using their savings.⁸⁰ The same survey also found that this number varied significantly with age and income, finding that only 33 percent of those in the millennial generation and

only 21 percent of those making less than \$30,000 per year would cover a hypothetical \$1,000 expense using savings.⁸¹ A survey by the Robert Wood Johnson Foundation found that 67 percent of those making less than \$35,000 per year reported they would have difficulty paying off a hypothetical \$1,000 expense.⁸² Research by the Pew Charitable Trust also found that 55 percent of Americans to be "savings-limited, meaning they can replace less than one month of their income through liquid savings."⁸³ For Americans at the bottom quintile of income, this amount is even less, with the typical family having less than 2 weeks of income in savings.⁸⁴

While research shows that some Americans are financially prepared to cover unexpected costs, many Americans are unable to weather such unexpected expenses.⁸⁵ The Pew Charitable Trust found that more than half of families that experienced a financial shock (such as an unplanned expense or loss of income) reported having trouble making ends meet, and this number increased for younger, minority, and low-income households. The Pew Charitable Trust also found that households that experienced such events typically had lower savings and higher credit card debts than those that did not.⁸⁶

While health care costs are not the only unexpected expenses people face, they constitute a large source of surprise expenses. The Robert Wood Johnson Foundation found that 38 percent of lower-income Americans and 31 percent of middle-income Americans reported experiencing significant problems with paying medical bills.⁸⁷ Many Americans, particularly those who are uninsured, report that they went without needed care, or delayed care, due to costs. For example, the Federal Reserve found that 38 percent of those with incomes below \$40,000 went without some form of medical care in 2019.⁸⁸ Among uninsured individuals,

⁷⁴ Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: <https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf>.

⁷⁵ For example, 24 percent of adults went without some form of medical care due to an inability to pay, down from 27 percent in 2017 and well below the 32 percent reported in 2013. Dental care was the most frequently skipped treatment (17 percent), followed by visiting a doctor (12 percent) and taking prescription medicines (10 percent). Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2018 (May 2019), available at: <https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm>.

⁷⁶ Kluender R., Mahoney N., Wong F., Yin W. Medical Debt in the U.S., 2009–2020. JAMA. 2021;326(3):250–256. doi:10.1001/jama.2021.8694.

⁷⁷ Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2018 (May 2019), available at: <https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm>.

⁷⁸ Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: <https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf>.

⁷⁹ Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: <https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf>.

⁸⁰ <https://www.bankrate.com/banking/savings/financial-security-january-2021/>.

⁸¹ <https://www.bankrate.com/banking/savings/financial-security-january-2021/>.

⁸² <https://www.rwjf.org/en/library/research/2019/12/life-experiences-and-income-inequality-in-the-united-states.html>.

⁸³ https://www.pewtrusts.org/-/media/Assets/2015/01/FSM_Balance_Sheet_Report.pdf.

⁸⁴ https://www.pewtrusts.org/-/media/Assets/2015/01/FSM_Balance_Sheet_Report.pdf.

⁸⁵ https://www.pewtrusts.org/-/media/assets/2015/10/emergency-savings-report-1_artfinal.pdf.

⁸⁶ https://www.pewtrusts.org/-/media/assets/2015/10/emergency-savings-report-1_artfinal.pdf.

⁸⁷ <https://www.rwjf.org/en/library/research/2019/12/life-experiences-and-income-inequality-in-the-united-states.html>.

⁸⁸ <https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm>.

47 percent went without some form of medical care due to concerns over costs.⁸⁹ Research reinforces the findings of the Federal Reserve and indicates that additional risk factors such as perceived health and depression increase an individual's likelihood of reporting that health care is unaffordable.^{90 91} For these groups facing high health care related financial burdens, which include those most likely to be uninsured and underinsured,⁹² unexpected expenses of \$400 or more would reasonably constitute a substantial amount.

HHS also considered setting the flat dollar lower than \$400. However, as discussed in greater detail in section VI.B.8 of this preamble, HHS expects to contract with SDR entities directly and will pay the SDR entity costs. Based on conversations with stakeholders and research of similar state processes, HHS found that the amount that dispute resolution entities charge for similar dispute resolution processes is around \$400 per case. A study by the Commonwealth Fund similarly found costs for dispute resolution ranging between \$300 and \$600.⁹³ HHS found that other state dispute resolution processes could potentially charge the uninsured (or self-pay) individual high fees to initiate a dispute. For example, in New York, the cost to the uninsured (or self-pay) individual for dispute resolution could be as much as \$395, and in Maine as much as \$450.⁹⁴ However, as is further discussed in section VI.B.8 of this preamble, HHS

will only charge a small administrative fee, meaning that uninsured (or self-pay) individuals will be mostly insulated from the costs of dispute resolution. HHS acknowledges that the costs to the government for conducting dispute resolution would not be a consideration for the uninsured (or self-pay) individual in determining whether to initiate a dispute, as they would not be required to pay those costs. However, HHS is of the view that it would not make sense to conduct dispute resolution cases where the amount in dispute is less than the cost for the dispute resolution entity. As a result, HHS is of the view that setting the substantially-in-excess floor equal to \$400 is a reasonable and appropriate approach and would ensure that the minimum amount in dispute for the patient-provider dispute resolution process is comparable to the expected costs for dispute resolution.

In addition, HHS considered whether to set the substantially-in-excess threshold floor at a higher amount than \$400. However, HHS remains concerned that setting the flat dollar floor for the substantially-in-excess threshold greater than \$400 could ultimately result in many uninsured (or self-pay) individuals, particularly those who received lower cost items or services, being unable to access the patient-provider dispute resolution process. As a result, HHS is of the view that limiting patient-provider dispute resolution to items or services where the total billed charges exceed the total expected charges in the good faith estimate by \$400 or greater strikes the appropriate balance that helps ensure that amounts in dispute are sufficiently large to justify the costs of maintaining and operating the dispute resolution process; that burdens on providers, facilities, and the Federal Government are minimized; and that all uninsured (or self-pay) individuals are able to access the dispute resolution process to resolve unexpected billed amounts.

As HHS obtains additional experience with the patient-provider dispute resolution process, HHS intends to review data on the use of the process, such as the volume of dispute resolution cases, differences between the total expected charges in the good faith estimate and the total billed charges in cases that go to dispute resolution, data on payment determination amounts by SDR entities, the success rate for uninsured (or self-pay) individuals who initiate dispute resolution, and characteristics of initiation requests that are determined ineligible, and in future years may propose adjustments to the definition of "substantially in excess."

HHS seeks comment on the definition for "substantially in excess," including whether the \$400 amount should be set higher or lower, whether there is any other specific dollar value that would be more appropriate, or whether a different method for determining "substantially in excess" should be considered. HHS also seeks 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. HHS also seeks comment on how these definitions may impact market incentives, including the accuracy of good faith estimates.

3. Eligibility for Patient-Provider Dispute Resolution

The patient-provider dispute resolution process in PHS Act section 2799B-7 applies to uninsured (or-self-pay) individuals who received, pursuant to PHS Act section 2799B-6, a good faith estimate of the expected charges for scheduled or requested items or services from a provider or facility, and who after being furnished such item or service is billed by such provider or facility charges substantially in excess of such estimate. To clarify what items and services are eligible for the patient-provider dispute resolution process, HHS is adding 45 CFR 149.620(b) which specifies that items or services provided by a convening provider, convening facility, co-provider, or co-facility are eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610, regardless of whether the items or services included in the total billed charges were listed in the good faith estimate, or whether the co-provider or co-facility was listed on the good faith estimate.

Good faith estimates for scheduled items or services, or when requested, as specified in 45 CFR 149.610, are intended to provide a comprehensive estimate of expected charges for items or services furnished during the period of care. PHS Act section 2799B-6 and 45 CFR 149.610 require providers or facilities to include any item or service that is reasonably expected to be provided in conjunction with an item or service, including an item or service reasonably expected to be so provided by another provider or facility.

HHS is of the view that an uninsured (or self-pay) individual should be able

⁸⁹ <https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm>.

⁹⁰ Kielb E.S., Rhyan C.N., Lee J.A. Comparing Health Care Financial Burden With an Alternative Measure of Unaffordability. *Inquiry*. 2017;54:46958017732960. doi:10.1177/0046958017732960.

⁹¹ Amin K., Claxton G., Ramirez G., Cox C. How Does Cost Affect Access to Care? *Peterson-KFF Health System Tracker*. January 2021. Available at <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start>.

⁹² Kielb E.S., Rhyan C.N., Lee J.A. Comparing Health Care Financial Burden With an Alternative Measure of Unaffordability. *Inquiry*. 2017;54:46958017732960. doi:10.1177/0046958017732960. Also see, Amin K., Claxton G., Ramirez G., Cox C. How Does Cost Affect Access to Care. *Peterson-KFF Health System Tracker*. January 2021. Available at <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start>. Also see, Tolbert J., Orgera K., Key Facts About the Uninsured Population. *Kaiser Family Foundation*. November 2020. Available at <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>.

⁹³ <https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise>.

⁹⁴ https://www.dfs.ny.gov/system/files/documents/2020/10/idr_patient_application.pdf and <https://dispute.maximus.com/me/indexME>.

to initiate the patient-provider dispute resolution process when the total billed charge for an item or service from a particular provider or facility represented in the good faith estimate exceeds the substantially in excess threshold defined at 45 CFR 149.620(a)(2). Therefore, these interim final rules specify that an item or service provided by a convening provider, convening facility, co-provider or co-facility are eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider or facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the of total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610.

As an example, an uninsured (or self-pay) individual receives a good faith estimate that lists expected charges for 3 services, A, B, and C. Services A and B are provided by provider Y and service C is provided by co-provider Z. The total billed charges for services A and B must exceed the total expected charges for services A and B by at least \$400 more than the amount listed in the good faith estimate in order for the uninsured (or self-pay) individual to be eligible to initiate patient-provider dispute resolution against provider Y. Similarly, the billed charge for service C must exceed the expected charges for service C by at least \$400 more than the amount listed in the good faith estimate in order for the uninsured (or self-pay) individual to be eligible for the patient-provider dispute resolution against co-provider Z.

An item or service is eligible for patient-provider dispute resolution based on the total billed charges from the provider or facility, regardless of whether such items or services are included in a good faith estimate. HHS recognizes that unforeseen factors during the course of treatment may occur, which could involve additional items or services from providers and facilities, and may result in higher billed charges after receipt of care than was anticipated at the time the good faith estimate was provided to the uninsured (or self-pay) individual. However, HHS is of the view that if an item or service is eligible for patient-provider dispute resolution only if it is explicitly listed in the good faith estimate, providers and facilities may be incentivized to omit items and services from the good faith estimate in order to avoid the patient-provider dispute resolution process. It is HHS's view that Congress intended to create a process which allows uninsured (or self-pay)

individuals to dispute the final billed charges, if such charges are substantially in excess of the expected charges in the good faith estimate; and therefore any item or service that was not included in the good faith estimate, yet resulted in total billed charges substantially in excess of the total expected charges in the good faith estimate, should be eligible for patient-provider dispute resolution.

Therefore, if the total billed charges, which includes charges for new items or services, exceeds the total expected charges by at least \$400 more than the amount in the good faith estimate, the items or services are eligible for patient-provider dispute resolution, despite the new items or services not being itemized in the good faith estimate. For example, co-provider Z bills an uninsured (or self-pay) individual for services C, D, and E, even though services D and E were not included in the good faith estimate. If the differences between the total billed charges for services C, D, and E are substantially in excess of the total expected charges in the good faith estimate for service C, then the uninsured (or self-pay) individual is eligible to initiate patient-provider dispute resolution against co-provider Z for services C, D, and E.

Although convening providers and convening facilities are required to include expected charges from co-providers and co-facilities in the good faith estimate, HHS understands that there may be instances when an uninsured (or self-pay) individual may receive a bill that includes providers or facilities that were not included in the good faith estimate: Specifically, if a co-provider or co-facility that is reflected on the good faith estimate is substituted at the last moment to a different co-provider or co-facility. While PHS Act section 2799B-7 requires that an item or service where the total billed charges are substantially in excess of the total expected charges in the good faith estimate will be eligible for patient-provider dispute resolution, expected charges for the replacement co-provider or co-facility may not be available. Regardless, HHS is of the view that the consumer protections of PHS Act section 2799B-7 should still apply in these circumstances as they are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills, and allowing a co-provider or co-facility to circumvent these protections simply due to not being directly represented on the good faith estimate would undermine these protections. Therefore, HHS is adding 45 CFR 149.620(b)(2) that specifies that an item

or service billed by a co-provider or co-facility that replaced the original co-provider or co-facility covered under a good faith estimate is eligible for dispute resolution if the total billed charge is substantially in excess of the expected charges included on the good faith estimate for the original co-provider or co-facility. However, if the replacement co-provider or co-facility provides the uninsured (or self-pay) individual with a new good faith estimate of expected charges in accordance with 45 CFR 149.610(b)(2) then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charges for the replacement co-provider or co-facility are substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

HHS is of the view that had the convening provider known that the items or services from these particular co-providers or co-facilities would be needed, they would have been included on the good faith estimate. Therefore, HHS is of the view that such an approach for an item or service billed by a replacement co-provider or co-facility is necessary and appropriate to ensure such item or service is eligible for dispute resolution if the total billed charges are substantially in excess of the total expected charges in the good faith estimate even if the billing provider or facility did not provide the original estimate of expected charges in the good faith estimate. HHS acknowledges the challenges these requirements impose on providers and facilities, and the potential disincentive that such a requirement could have on a provider's or facility's willingness to provide an item or service under such circumstances given the patient-provider dispute resolution process, at 45 CFR 149.620, uses the expected charges contained in the good faith estimate to determine the eligibility of an item or service for patient-provider dispute resolution. However, HHS is of the view that such requirements are necessary for the intended consumer protections regarding surprise medical bills, and that, without such a requirement, an uninsured (or self-pay) individual may be unable to avail themselves of the patient-provider dispute resolution process in these circumstances. HHS also recognizes that these particular situations may be more complex for an uninsured (or self-pay) individual to determine eligibility for dispute resolution. HHS seeks comment

on the approach for eligibility in cases where the co-provider or co-facility has been replaced with a different co-provider or co-facility, comments on whether there are other complex situations where clarification would be helpful, and the feasibility of such an approach to eligibility, as well as comments on alternative approaches.

HHS considered whether to base eligibility for patient-provider dispute resolution on whether an individual item or service listed on a good faith estimate is billed an amount substantially in excess of the expected charge for the item or service. However, HHS is of the view that basing the eligibility for patient-provider dispute resolution on each individual item or service would add complexity as each item or service listed on the good faith estimate would need to be assessed separately for eligibility. Additionally, by basing the eligibility for patient-provider dispute resolution on an individual item or service, providers and facilities could potentially avoid dispute resolution by ensuring that no single billed charge exceeds the estimate provided on the good faith estimate by more than the substantially in excess threshold, even though the total of all billed charges for a provider or facility might substantially exceed the total expected charges in the good faith estimate. As a result, to fully protect the uninsured (or self-pay) individual, the individual items and services would need to be totaled by provider or facility, with the total billed charges by provider or facility subject to the substantially in excess standard. HHS is of the view that, because the uninsured (or self-pay) individual understood the items or services to most likely cost the amount listed in the good faith estimate with respect to each provider or facility, focusing on the total billed charges by each provider or facility ensures that patient-provider dispute resolution is available when the total billed charges for each provider or facility substantially exceeds the amount that the individual expects to pay.

HHS also considered basing the eligibility on the total billed charges for all items or services and all providers or facilities listed on the good faith estimate. However such an approach would be significantly more complex given that the good faith estimate could consist of estimates from multiple providers and facilities who would bill the uninsured (or self-pay) individual separately. It could also potentially increase the burden on the uninsured (or-self pay) individual who would likely need to submit multiple bills from multiple providers or facilities.

Additionally, such an approach could require a provider or facility to respond to a notice requesting additional documentation from an SDR entity due to the billing of other providers, even when the provider or facility did not bill an uninsured (or self-pay) individual an amount substantially in excess of the good faith estimate.

As discussed in section VI.A.2 of this preamble, these interim final rules define expected charges, for an item or service, as, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer. Therefore, HHS would anticipate that the expected charges in the good faith estimate include applicable discounts and rates the provider or facility would ultimately charge an uninsured (or self-pay) individual rather than a standard list price or chargemaster rate. However, HHS remains concerned about the potential incentives for providers and facilities to inflate good faith estimates, for example, by overestimating the costs for items or services, providing a higher list price (or chargemaster rate) rather than the price the uninsured (or self-pay) individual would be expected to pay when accounting for any discounts, upcoding to a more expensive service, or adding additional unnecessary services which could lead to higher good faith estimates overall and could discourage uninsured (or self-pay) individuals from obtaining needed care. Furthermore, HHS is also concerned that providers or facilities may interpret an individual's decision to seek care after receiving the good faith estimate as their ability to pay the expected charges and therefore be disincentivized to offer the uninsured (or self-pay) individuals with charity care or discounted rates. HHS acknowledges that the availability of the patient-provider dispute resolution process may lead providers or facilities to estimate prices higher than they otherwise would have. However, HHS is very concerned that a provider or facility may increase the good faith estimate amount specifically to circumvent the ability of the uninsured (or self-pay) individual to access the patient-provider dispute resolution process, resulting in uninsured (or self-pay) individuals

being charged higher prices and as a result the uninsured (or self-pay) individual foregoing needed care due to concerns over the potential costs. Additionally, this behavior could potentially lead to a situation where an uninsured (or self-pay) individual ultimately receives an inflated good faith estimate, but after receiving treatment is billed an amount higher than the good faith estimate yet less than the substantially in excess threshold, and is therefore unable to access dispute resolution due to the expected charges in the good faith estimate being overestimated. HHS acknowledges that an uninsured (or self-pay) individual may not necessarily know if a good faith estimate is inflated. However, as discussed in section VI.A.4 of this preamble, the good faith estimate will provide an itemized list of the expected items or services in advance, including the applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service. HHS is of the view that this will provide needed transparency for uninsured (or self-pay) individuals about the items or services they expect to be provided and the estimated costs with which they can compare with good faith estimates from other providers or through price transparency information such as the Hospital Price Transparency requirements described in 45 CFR part 180. HHS seeks comment on what other resources are available to assist individuals in determining the reasonableness of the good faith estimates they receive, particularly those who are uninsured (or self-pay) and with low health literacy. HHS also seeks comments on ways to raise awareness of these resources and on other resources that could be utilized by uninsured (or self-pay) individuals.

HHS notes that a provider or facility intentionally providing expected charges they know to be incomplete or inaccurate in the good faith estimate could violate the requirements in PHS Act section 2799B–6, which requires that the estimates being provided be good faith estimates, and thus could be subject to enforcement actions under PHS Act section 2799B–4. HHS is of the view that it is important for an uninsured (or self-pay) individuals to be able to file complaints regarding a provider or facility who they believe is not complying with the good faith estimate requirements and patient-provider dispute resolution process requirements, such as in cases where an individual believes a provider or facility is inflating the good faith estimate.

Therefore, HHS is amending the regulations at 45 CFR 149.450 to expand the scope to include subpart G of part 149, which includes 45 CFR 149.610 and 45 CFR 149.620, among the provisions for which HHS can receive and resolve complaints concerning a provider's or facility's failure to meet the specified requirements. HHS seeks comment on this approach.

HHS also considered whether there should be an additional backstop that would allow an uninsured (or self-pay) individual to access patient-process dispute resolution based on allegations that the provider or facility willfully overestimated the expected charges in the good faith estimate in order to avoid dispute resolution. Under such an approach, the good faith estimate would be reviewed to ensure that the good faith estimate reasonably reflect only the expected charges for the item or service, and that the good faith estimate did not include items or services extraneous to those that were reasonably expected to be provided in conjunction with such scheduled item or service. If HHS were to determine that such requirements had not been met, the uninsured (or self-pay) individual would be deemed eligible to initiate the patient-provider dispute resolution process for such items or services. However, these interim final rules do not include such an approach as HHS was concerned this approach would add significantly more complexity to the patient-provider dispute resolution process. HHS seeks comment on this potential approach of allowing uninsured (or self-pay) individuals to initiate dispute resolution for good faith estimates they believe to have been overinflated in order for providers and facilities to avoid dispute resolution.

As noted elsewhere in this preamble, with regards to an item or service furnished by co-providers and co-facilities, providers and facilities subject to these interim final rules may need additional implementation time to develop appropriate communication channels that may not yet exist among various co-providers or co-facilities. As stated in section VI.A.7 of this preamble, with respect to good faith estimates provided to uninsured (or self-pay) individuals on or after January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where the good faith estimate does not include expected charges for items and services from a co-provider or co-facility. During this period, HHS encourages convening providers and facilities to include a range of expected charges for such items and services during the period of care.

HHS understands that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information regarding items and services provided by co-providers and co-facilities. HHS is of the view that without having such processes in place, co-providers and co-facilities who provide items or services may be subjected to patient-provider dispute resolution in situations where the co-providers or co-facilities were unable to provide complete and accurate pricing information to the convening provider or facility, and as a result would not provide sufficient detail to provide accurate good faith estimates. As a result, during the period of enforcement discretion, further discussed in section VI.A.7 of this preamble, items or services to be provided by a co-provider or co-facility that appear on the good faith estimate that do not include an estimate of expected charges or that appear as a range of expected charges would not be eligible for the patient-provider dispute resolution process. However, HHS emphasizes that this particular application for patient-provider dispute resolution eligibility would apply only in 2022 to allow additional time for the convening provider and convening facility to build the necessary systems and processes to receive accurate estimates from co-providers and co-facilities. HHS notes, that nothing prevents a co-provider or co-facility from furnishing the information as required in 45 CFR 149.610 before December 31, 2022, and under such circumstances, a co-provider or co-facility must comply with the patient-provider dispute resolution requirements in 45 CFR 149.620. Additionally, nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or co-facility in which case the patient-provider dispute resolution requirements in 45 CFR 149.620 would apply. HHS seeks comment on the approach for eligibility for the patient-provider dispute resolution process, including the feasibility of such approach, including the approach for eligibility for co-providers and co-facilities in 2022, as well as comment on alternative approaches to increase consumer protections against unexpected medical bills from co-providers and co-facilities during 2022.

HHS also recognizes that uninsured (or self-pay) individuals in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations,

individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, may face additional barriers to paying for high unexpected health care costs, understanding their rights related to good faith estimates, patient-provider dispute resolution, and how and when to initiate the dispute resolution process. HHS seeks comment from underserved and racial/ethnic minority communities on additional barriers individuals from these communities may face in understanding and exercising their rights related to these topics, and how to address them. HHS also seeks feedback on outreach and education activities, efforts, and resources available for underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, to help ensure that these rights and tools are available, accessible, and understood such that they can be used equitably by all uninsured (or self-pay) individuals in appropriate circumstances. HHS also recognizes that groups such as CAPs and legal aid organizations play an important role in helping consumers, particularly those in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations; individuals with limited English proficiency; and persons with health literacy needs, with complex health care issues, which may also include assistance with the patient-provider dispute resolution process. HHS seeks comment on how to best to support the efforts of these organizations in assisting uninsured (or self-pay) individuals throughout the patient-provider dispute resolution process.

4. Initiation of Patient-Provider Dispute Resolution

PHS Act section 2799B-7 requires patient-provider dispute resolution be available when an uninsured (or self-pay) individual is billed by a provider or facility for items or services in an amount that is "substantially in excess" of the expected charges in the good faith estimate for the provider or facility.

HHS is specifying under 45 CFR 149.620(c) that when an uninsured (or self-pay) individual is billed for items or services where the total billed charges for a provider or facility is substantially in excess of the total expected charges in the good faith estimate for the

provider or facility, the uninsured (or self-pay) individual or their authorized representative (excluding any providers or facilities directly represented in the good faith estimate, providers associated with such providers or facilities, or non-clinical staff associated with such providers or facilities), may submit a notification (initiation notice) to the Secretary of HHS to initiate the patient-provider dispute resolution process. HHS is of the view that a provider should generally not be permitted to represent the uninsured (or self-pay) individual in dispute resolution for items or services where the provider was represented on the good faith estimate, even if the provider would not be a party to the dispute. HHS is of the view that there is a 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. However, HHS acknowledges that many providers would generally not be inclined to assist the uninsured (or self-pay) individuals with initiating a dispute resolution even without this restriction. HHS further clarifies that providers may serve as authorized representatives for uninsured (or self-pay) individuals, provided they do not meet the previously described exclusion criteria. HHS also clarifies that CAPs and legal aid organizations can also serve as authorized representatives for the purpose of the patient-provider dispute resolution process as such organizations may have experience assisting consumers with billing issues. Additionally, all materials created for the patient-provider dispute resolution process, including the Federal IDR portal, will be compliant with the language access requirements of section 508 of the Rehabilitation Act of 1973 to meet accessibility needs.⁹⁵ HHS seeks comment on what additional supports are necessary for community organizations, such as CAPs and legal aid organizations, to assist uninsured (or self-pay) individuals with the dispute resolution process. Providers and facilities are also required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds providers and facilities that are recipients of Federal financial assistance that they must

comply with Federal civil rights laws that prohibit discrimination. These laws may include Section 1557 of the Patient Protection and Affordable Care Act, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973, as applicable. Section 1557 of the Patient Protection and Affordable Care Act and Title VI of the Civil Rights Act of 1964 require covered entities to take reasonable steps to ensure meaningful access for individuals with limited English proficiency, which may include provision of language assistance services, such as providing qualified interpreters or written translation of written good faith estimates in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely manner and free of charge 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. HHS also seeks comment on what additional supports are necessary for persons in and representatives of minority and underserved communities, including those with limited English proficiency, those with disabilities who require information in alternate and accessible formats, and stakeholders who serve such communities.

The initiation notice must be submitted to the Secretary of HHS, and postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate, for the provider or facility. HHS is specifying calendar days instead of business days in this instance, because it is HHS' experience in administering other consumer-facing programs such as the Federally Facilitated Marketplace, that consumers have an easier time calculating and responding to deadlines that are measured by calendar days rather than business days. HHS

considered whether to specify a timeframe shorter than 120 calendar days. However, HHS is concerned that requiring the initiation notice to be submitted in less than 120 calendar days would not provide sufficient time for an uninsured (or self-pay) individual to collect and submit the required information. HHS also considered a timeframe greater than 120 calendar days, or no time limit; but HHS is of the view that due to the requirement, as discussed later in this section, that once the patient-provider dispute resolution process has been initiated, a provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts, as well as the requirement that the provider or facility suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded, providing for a longer timeframe could increase uncertainty for a provider or facility over whether an uninsured (or self-pay) individual will file a dispute resolution request. As a result, HHS is of the view that having a clear timeframe with which an uninsured (or self-pay) individual can initiate a dispute resolution request is both necessary and appropriate. HHS seeks comment on the appropriateness of allowing individuals 120 calendar days to initiate the dispute resolution process, and whether more or less time should be allowed for an uninsured (or self-pay) individual to initiate dispute resolution, or whether there should not be a time limit at all.

The initiation notice may be submitted through the Federal IDR portal, electronically, or on paper, in a form and manner specified by the Secretary of HHS. The initiation notice must include: (1) Information sufficient to identify the items or services under dispute, including the date of service or date the item was provided and a description of the item or service; (2) a copy of the bill for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (3) a copy of the good faith estimate for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (4) the contact information of the parties involved, including name, email address, phone number and mailing address; (5) the state where the items or services in dispute were furnished; and (6) the uninsured (or self-pay) individual's

⁹⁵ For 508 standards, see the US Access Board's final rule at: <https://www.federalregister.gov/documents/2017/01/18/2017-00395/information-and-communication-technology-ict-standards-and-guidelines>; see also *Information and Communication Technology Revised 508 Standards and 255 Guidelines*, U.S. Access Board, <https://www.access-board.gov/ict/> (last visited Sept. 10, 2021).

communication preference, through the Federal IDR Portal, or electronic or paper mail.

In addition to the required information, the uninsured (or self-pay) individual must submit with the initiation notice an administrative fee to the SDR entity as described in 45 CFR 149.620(g) and section VI.B.8 of this preamble. The amount of the administrative fee, as well as the manner in which it must be submitted, will be clarified in guidance by HHS. PHS Act section 2799B-7(c) contemplates that the uninsured (or self-pay) individual pay an administrative fee, and that such fee should be set in a manner not to create a barrier to access the process. While HHS acknowledges that requiring an uninsured (or self-pay) individual to pay an administrative fee upfront may discourage some individuals from initiating the patient-provider dispute resolution process, HHS is of the view that requiring a nominal upfront administrative fee will help prevent the submission of unnecessary claims to the patient-provider dispute resolution process and ensure that dispute resolution resources are available in necessary cases. HHS also notes that as further discussed in section VI.B.8 of this preamble, if the uninsured (or self-pay) individual prevails in the dispute resolution process, the SDR entity will adjust the final payment determination amount to include a reduction in the final payment determination amount that accounts for the uninsured (or self-pay) individual's administrative fee payment, thus allowing the uninsured (or self-pay) individual to recoup the administrative fee paid.

The date of initiation of the patient-provider dispute resolution process will be the date of receipt of such initiation notice. HHS will provide additional information in guidance on how the uninsured (or self-pay) individual can submit the initiation notice, including necessary steps for the process and a standard notification form to ensure the uninsured (or self-pay) individual is able to include all the necessary information to initiate the dispute resolution process. In addition to the guidance, uninsured individuals will be informed of how to initiate the patient-provider dispute resolution process through information that providers and facilities must include on the good faith estimates, as discussed in section VI.A.4 of this preamble. HHS also intends to conduct outreach and education to consumer advocates, CAPs, legal aid organizations and other stakeholders to assist consumers through this process.

HHS expects to leverage the Federal IDR portal described in section III of this preamble to facilitate the operation of the patient-provider dispute resolution process. The Federal IDR portal will allow uninsured (or self-pay) individuals or their authorized representatives to submit the initiation notices, upload documentation, receive notices from HHS and the SDR entity, upload additional supporting documentation, and view the SDR entity's payment determination. HHS expects that providers and facilities will also utilize the Federal IDR portal to receive notices from HHS and the SDR entity, upload documentation, upload additional supporting documentation, and view the SDR entity's determination. HHS intends for the SDR entity to utilize the Federal IDR portal in all cases, as HHS is of the view that utilizing the Federal IDR portal to facilitate the patient-provider dispute resolution process is preferable and will allow for more efficient operation of the process, faster and easier receipt of notices and submission of documentation, and would allow all the relevant information on a specific patient-provider dispute resolution case to be accessible in one place. HHS is aware that an individual or a provider or facility may not be able to utilize the Federal IDR portal depending on various factors and as a result the individual, provider, or facility may choose to communicate with HHS or the SDR entity using other methods, including electronic or paper mail. Additionally, HHS recognizes that minority and underserved communities, including those with limited English proficiency and those with disabilities may prefer information in alternate and accessible formats and may not be best served by using the Federal IDR portal. HHS intends to put in place processes to ensure accessibility of the system for these communities, and HHS seeks comments on this approach.

Once the initiation notice has been received, HHS will select an SDR entity according to the process further described in section VI.B.6 of this preamble. After the SDR entity has been selected, the SDR entity will provide notice to the uninsured (or self-pay) individual and the provider or facility through the Federal IDR portal, or electronic or paper mail, that a patient-provider dispute resolution initiation request has been received and is under review, the SDR entity will also include information identifying the item or service under dispute, and the date the initiation notice was received. The SDR entity will also notify the uninsured (or

self-pay) individual, and the provider or facility, that while the dispute resolution process is pending, the provider or facility must not move bills for the disputed items or services into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts until the dispute has been settled. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded. Additionally, the provider or facility must not take or threaten to take retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process. The notice will also provide information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist them with the dispute.

The SDR entity will review the initiation notice submitted by the uninsured (or self-pay) individual to ensure that the disputed items or services meet the eligibility criteria for the patient-provider dispute resolution process and that the initiation notice contains all the required information. The SDR entity will notify the uninsured (or self-pay) individual electronically or by mail, depending on the individual's preference, of the outcome of the review including in cases where the initiation notice is determined to be incomplete or the item or service is determined ineligible for dispute resolution, in which case the uninsured (or self-pay) individual would be provided 21 calendar days to submit any missing information or provide supplemental information to demonstrate the item or service is eligible for the dispute resolution process. To assist consumers with understanding the timeline to submit the supplemental information, such insufficiency notice will provide a date by which the additional information must be postmarked or submitted electronically. HHS is of the view that providing the uninsured (or self-pay) individual with 21 calendar days is appropriate as it provides consumers with an opportunity to resolve any deficiencies in the initiation notice and access the dispute resolution process if eligible. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar day extension will be granted to allow sufficient time for document

submission, so that the individual, in this situation, will have a total of 35 calendar days to submit supplemental information. HHS also considered a timeframe greater than 21 calendar days, or no time limit, however, HHS is concerned that due to the requirement that a provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts, and the provider or facility suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded, providing for a longer timeframe could increase burdens and uncertainty for a provider or facility. The 21-calendar-day timeframe is also consistent with external review processes in some states.⁹⁶ HHS seeks comments on whether 21 calendar days is a sufficient timeframe for uninsured (or self-pay) individuals to submit additional documentation through the mail or electronically, or whether a different timeframe should be considered.

Once the SDR entity has determined that an item or service is eligible for dispute resolution, the SDR entity must provide notification of the determination to both parties (the uninsured (or self-pay) individual and the provider or facility) through the Federal IDR portal, or electronic or paper mail, and must request that the provider or facility provide certain information within 10 business days as described in 45 CFR 149.620(d) and in section VI.B.7.ii of this preamble.

While the dispute resolution process is pending, the provider or facility must not move bills for the disputed items or services into collection or threaten to do so until after dispute resolution process has concluded, or if the bill has already moved into collection, the provider or facility should cease collection efforts until the dispute has been settled. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded. PHS Act section 2799B–7 established a process that would provide a mechanism for an uninsured (or self-pay) individual who is billed an amount for an item or service that is substantially in excess of the expected charges in the good faith estimate to seek a determination on the amount to be paid. If the provider or facility were

to move the bill, if fully or partially unpaid, to collection or to accrue late fees prior to the SDR entity determining a payment amount, the consumer protections intended in PHS Act section 2799B–7 would be undermined. In order for an uninsured (or self-pay) individual to avoid moving the bill into collection or the accrual of late fees, the uninsured (or self-pay) individual would effectively be required to pay the bill in full prior to determination and seek a refund from the provider or facility if the individual prevails. HHS is of the view that through the patient-provider dispute resolution process, the uninsured (or self-pay) individual is actively working in good faith to resolve a payment dispute and should not be effectively punished for utilizing such process by the accrual of late fees or movement of the bill into collections. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary and appropriate in order to implement the provisions of PHS Act section 2799B–7 in a manner that furthers the statutory intent to protect consumers by ensuring that uninsured (or self-pay) individuals can use the patient-provider dispute resolution process without being penalized for utilizing such process or being required to pay the billed charges upfront to avoid late fees or collections activities. HHS seeks comment on this approach of disallowing the movement of a bill into collections and the suspension of the accrual of late fees.

In addition, HHS is using its general rulemaking authority to establish requirements under 45 CFR 149.620 to prohibit a provider or facility from taking or threatening to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service. If a provider or facility were to take or threaten to take retributive action against an uninsured (or self-pay) individual, such action could create a chilling effect for the uninsured (or self-pay) individual to utilize the dispute resolution process, which would undermine the consumer protections intended in PHS Act section 2799B–7. As a result, HHS is of the view that it is necessary and appropriate to require a provider or facility to not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process.

5. Certification of Selected Dispute Resolution Entities

PHS Act section 2799B–7 requires the Secretary of HHS to recognize or

establish a process to contract with and certify entities to resolve payment disputes between uninsured (or self-pay) individuals. Additionally, PHS Act section 2799B–7 requires entities certified under this process to satisfy, at a minimum, the criteria in PHS Act section 2799A–1(c). HHS intends to contract with and certify only that number of entities it believes will be necessary to timely resolve the volume of patient-provider disputes, rather than pursue an open process under which all entities who meet IDR entity requirements will be certified to resolve patient-provider payment disputes. Moreover, HHS will compensate SDR entities directly for their services under a contract that complies with the Federal Acquisition Regulation (FAR) as further implemented or supplemented by the HHS Acquisition Regulation.⁹⁷ Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements. HHS is of the view that this approach will reduce the overall cost of the program, which is funded primarily through appropriations to HHS, reduce the administrative burden associated with collecting fees from a large number of certified entities who may have differing fee schedules, and will allow for HHS to control the cost of the program to ensure that low-income individuals are able to access the patient-provider dispute resolution process. For the first year of the patient-provider dispute resolution program under PHS Act section 2799B–7, HHS anticipates contracting with between 1 and 3 SDR entities. HHS is of the view that 1 to 3 SDR entities will be sufficient in the first year to conduct the dispute resolution process for the anticipated number of cases outlined in the Economic Impact and Paperwork Burden section of these interim final rules. It will also ensure through the contracting process that the volume estimates are tenable for the contracted SDR entities. Additionally, given the timeline required by statute to implement the patient-provider dispute resolution process and the timeline under which these rules will become effective, HHS is of the view that contracting with a limited number of entities may be necessary to ensure the timely launch of the program.⁹⁸ HHS is of the view that attempting to procure

⁹⁷ See 48 CFR, Chapter 3 (HHS-specific regulations governing federal acquisitions for services).

⁹⁸ See FAR 6.302–2 (allowing less than full and open competition where an agency's need for services is of an unusual and compelling urgency).

⁹⁶ Some state processes have a 15-business day time frame which would generally translate to 21 calendar days. See e.g., <https://insurance.mo.gov/consumers/health/externalreviewprocess.php>.

SDR entity services from more than 3 entities will increase the burden associated with certifying IDR entities for the Federal IDR process discussed in section III of this preamble and with contracting SDR entities for the patient-provider dispute resolution process, and will limit HHS' ability to effectively launch the programs in accordance with statutory deadlines. HHS also is of the view that contracting with more than 3 SDR entities in the first year will unsustainably increase the administrative burden associated with launching both programs, and may impose sufficient risk to cause delays in implementation.

For these reasons, HHS is of the view that contracting with a limited number of SDR entities is preferable to adopting an "any willing provider" model. Accordingly, through this contract process, HHS will assess an entity's compliance with the SDR entity certification requirements to ensure the entity satisfies the certification criteria discussed later in this section of the preamble.

SDR entities will be assessed on whether they meet the applicable certification requirements during the contracting process with HHS and such process will be separate and distinct from the certification process applicable to IDR entities that will provide IDR services for providers, providers of air ambulance services, facilities, plans and issuers as required under 26 CFR 54.9816-8T and 54.9817-2T, 29 CFR 2590.716-8 and 2590.717-2, and 45 CFR 149.510, and 45 CFR 149.520. Although an SDR entity may apply for certification as an IDR entity, SDR entities are not required to do so. However, consistent with the statutory requirement, SDR entities will be required to meet the same requirements as certified IDR entities, with a few exceptions outlined later in this section of this preamble. SDR entities will be required to report on those data elements from providers and facilities that HHS deems necessary to accurately describe and assess the administration of the patient-provider dispute resolution program. Therefore, the requirements laid out in section III.D.5 of this preamble will also apply to SDR entities as a condition of receiving a contract award from HHS for the patient-provider dispute resolution program.

For example, PHS Act section 2799A-1(c)(4)(A)(v) requires a certified IDR entity to maintain the confidentiality of individually identifiable health information (IIHI) obtained in the course of conducting determinations. Under these interim final rules, HHS outlines

certain standards related to confidentiality, including security, privacy, and breach notification requirements that apply to an IDR entity seeking certification. See section III.D.5 of this preamble for further discussion on the applicable confidentiality requirements. Under 45 CFR 149.620(d)(1), HHS specifies that an SDR entity must satisfy the Federal IDR entity certification criteria specified in 45 CFR 149.510(e), with a few exceptions specified in 45 CFR 149.620(d)(2). As part of this requirement, an SDR entity must comply with all the confidentiality requirements that apply to certified IDR entities in 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v) and 45 CFR 149.510(e)(2)(v). Similarly, the definitions related to confidentiality in 45 CFR 149.510(a)(2) also apply for 45 CFR 149.620. Therefore, the definitions for "breach," "individually identifiable health information (IIHI)" and "unsecured IIHI" that apply for IDR entities also apply for SDR entities. HHS seeks comment on the confidentiality requirements for an SDR entity, including whether additional requirements should be considered.

In addition, like IDR entities, SDR entities are required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds SDR entities that they, along with providers and facilities that are recipients of Federal financial assistance, must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973. Section 1557 of the Patient Protection and Affordable Care Act and title VI of the Civil Rights Act of 1964 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 providing qualified interpreters or written translations in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 of the Patient Protection and Affordable Care Act and Section 504 of the Rehabilitation Act of 1973 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely

manner and free of charge to the individual. Auxiliary aids and services may include sign language 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. HHS also seeks comment on what additional measures are necessary for persons in racial/ethnic minority and underserved communities, including those with limited English proficiency, those with disabilities who require information in alternate and accessible formats, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and stakeholders who serve such communities.

Unlike the process for certifying IDR entities, HHS intends to contract only with SDR entities that will be able to conduct patient-provider dispute resolution in all applicable states where the patient-provider dispute resolution process will apply. As such, SDR entities will need to submit information on their ability to operate nationwide through the contract process. Additionally, IDR entity fees that certified IDR entities will charge as the cost for providing dispute resolution services will not apply in the case of SDR entities, which will be paid for their services through contracts with HHS. Therefore, SDR entities will not be required to submit a fee schedule for batched and non-batched claims. Additionally, SDR entities will not be required to submit policies and procedures regarding holding IDR entity fees in a trust or escrow account, though they will still be required to submit policies and procedures regarding holding administrative fees and remit them to HHS in a manner specified by HHS.

Additionally, an SDR entity must also submit a conflict-of-interest mitigation policy that will not apply to IDR entities. Given that HHS intends to contract with a limited number of SDR entities under this program, HHS is of the view that additional standards for conflict-of-interest mitigation should apply to SDR entities, as there will likely be fewer entities available to conduct dispute resolution. Therefore, in addition to the requirement for certified IDR entities to submit policies and procedures for the ongoing auditing, mitigation, and reporting of conflicts of interest within their

organizations, SDR entities will be expected to include a mitigation plan for situations when no one in the entire organization will be able to conduct dispute resolution on a case due to an entity-level conflict of interest, which could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for that case. Since there is a possibility that a single SDR entity will be contracted for this process, or that all available SDR entities indicate a conflict of interest that cannot be mitigated, HHS is of the view that additional requirements must be applied through these regulations and the contracting process to ensure that in the event that an entity-level conflict of interest occurs, SDR entities will be able to initiate strategies to fairly and impartially resolve disputes in the absence of another available SDR entity. Through the acquisition process, HHS will ensure compliance with FAR subpart 9.5 regarding organizational and consultant conflicts of interest in order to mitigate the potential for entity-level conflicts of interest that may preclude all available SDR entities from fairly and impartially resolving disputes.

While details on expectations for documentation and review for certified IDR entities will come through guidance, similar details and documentation requests will be done through the acquisition process for SDR entities. As such, all requirements laid out in this section and the applicable requirements outlined in section III.D.5 of this preamble for certified IDR entities will be assessed through the Federal acquisition process to ensure SDR entities have sufficient expertise and capabilities to conduct dispute resolution cases for the patient-provider dispute resolution process.

In subsequent years, case volume and other factors as necessary will be used by HHS to determine and adjust the number of contracted SDR entities needed for the patient-provider dispute resolution process. HHS is of the view that this approach will reduce the overall cost and administrative oversight burdens of the program, which is funded primarily through appropriations to HHS. Since contracting will allow HHS to negotiate lower rates for conducting dispute resolution cases with a limited number of entities, rather than paying set fee schedules associated with each SDR entity as in the Federal IDR process, HHS will be able to reduce both costs to HHS and administrative burdens associated with collecting varying fees from a large number of entities. HHS

also is of the view that this approach will allow HHS to control the fees assessed to uninsured (or self-pay) individuals entering the patient-provider dispute resolution process to ensure that low-income individuals can participate in the process.

HHS seeks comment on the SDR entity contracting process, including the applicable certification requirements, specifically as to whether these are the appropriate standards regarding the patient-provider dispute resolution process, if additional standards should be applied, and if so, what those standards should be.

6. Selection of an SDR Entity for Patient-Provider Dispute Resolution

PHS Act section 2799B-7 requires the Secretary of HHS to provide a method to select a patient-provider dispute resolution entity to conduct individual dispute resolutions between patients and providers. As described more fully in section VI.B.5 of this preamble, during the first year of the program, HHS expects to contract with between 1 to 3 SDR entities to conduct patient-provider dispute resolutions.

Similar to the IDR process and for the same reasons described in section III.B.1 of this preamble, the general conflict-of-interest standards laid out in section III.B.1 of this preamble will also apply to SDR entities contracted by HHS for the patient-provider dispute resolution process. These standards include the mandatory period which prohibits personnel who have been a party to the payment determination being disputed, or who were employees or agents of such a party within 1 year immediately preceding dispute resolution assignment, from being assigned to a case.

As discussed in section VI.B.5 of this preamble, SDR entities will also be required to have in place an approved mitigation plan for addressing conflicts of interest. For example, such a mitigation plan could include processes under which any specific dispute resolution personnel who presents a conflict of interest could be walled off from having any role in or knowledge of the relevant payment dispute. To address conflicts of interest that exist at the entity level, the SDR entity could design a plan under which it would subcontract payment disputes to a different entity that meets SDR entity requirements. As part of the contract process, and as discussed in section VI.B.5 of this preamble, the SDR entity must submit specific mitigation plans such as proof of a subcontractor who meets the SDR entity requirements for HHS to assess, and approve as part of

the acquisition process, and in accordance with the conflict-of-interest requirements set forth in FAR subpart 9.5. HHS is of the view that this approach will sufficiently mitigate the potential that conflicts of interest that exist to the extent that a case may not be able to be resolved fairly and impartially, because having a subcontractor provides an avenue for cases to be sent for dispute resolution when the SDR entity has a conflict of interest. HHS also is of the view that ensuring that processes are in place to identify and address potential conflicts of interest is important to ensure impartiality in payment determinations and the timely and efficient resolution of disputes.

Upon receiving a request to initiate patient-provider dispute resolution case from an uninsured (or self-pay) individual, HHS will select 1 of the contracted SDR entities to serve as the entity to conduct the dispute resolution process. Selection of an SDR entity that will resolve a particular dispute will occur in round robin fashion to ensure equal allocation of cases to SDR entities, unless conflicts of interest arise. In the event that the assigned SDR entity has a conflict of interest that cannot be sufficiently mitigated by applying the SDR entity's conflicts mitigation plan, the next SDR entity in line will be selected. HHS is of the view that this approach will help ensure the selection process runs smoothly, supports the timely resolution of disputes consistent with applicable regulations, and that SDR entity caseloads are allocated efficiently. Upon receiving an assignment from the Secretary of HHS to make a determination for an item or service, the SDR entity shall ensure that no conflict of interest exists, and in such case no conflict exists, the SDR entity shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity as described in section VI.B.4 of this preamble.

In the event that an SDR entity attests that a conflict of interest exists in relation to an assigned payment dispute, the SDR entity must notify the Secretary of HHS no later than 3 business days following selection. Additionally, either party (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days following receipt of the attestation.

In the event a conflict of interest exists, HHS will then automatically

select a different SDR entity from the remaining pool of contracted entities using a round robin approach. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed, to conduct dispute resolution in this case. HHS recognizes that while the Department expects these particular situations to be very rare, contracting with an additional SDR entity could take time and would make meeting the required patient-provider dispute resolution timeframes challenging. HHS notes that, as discussed in section VI.B.10 of this preamble, the time periods specified in these interim final rules may be extended in the case of extenuating circumstances at HHS' discretion on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. In these rare cases, HHS anticipates that it may be appropriate to exercise such discretion if needed. For example, in the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity. HHS seeks comment on this approach, including comment on the feasibility of such approach and comment on alternative approaches HHS should consider. HHS also seeks comment on whether it is feasible or appropriate to seek assistance from the pool of certified IDR entities to provide patient-provider dispute resolution services in these circumstances.

These interim final rules also define certain terms related to conflict-of-interest standards applicable to SDR entities certified and contracted to resolve patient-provider disputes. Such an approach to conflict of interest is similar to the approach taken by the Federal IDR process discussed in section III.D.5 of this preamble. HHS is of the view that maintaining consistent standards between the Federal IDR process and the patient-provider dispute resolution process is a straightforward approach and serves to minimize stakeholder confusion over what the applicable standard will be. In general, a "conflict of interest" means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment

determination. For purposes of the patient-provider dispute resolution process, a conflict of interest exists when an SDR entity is: A provider or a facility, an affiliate or a subsidiary of a provider or facility, or an affiliate or subsidiary of a professional or trade association representing a provider or facility. A conflict of interest also exists when an SDR entity, or any personnel assigned to a determination, has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute. HHS is of the view that these requirements are necessary to ensure that payment disputes between an uninsured (or self-pay) individual and a provider or facility are conducted by impartial third parties. HHS seeks comment on this approach, including the feasibility of such approach, and whether additional requirements related to conflict of interest should be considered.

7. Payment Determination for Patient-Provider Dispute Resolution

i. Determination of Payment Amount Through Settlement

While the SDR entity payment determination is pending, HHS recognizes that the two parties to the patient-provider dispute resolution process (the uninsured (or self-pay) individual and the provider or facility) may agree to resolve the dispute by settling on a payment amount. Therefore, new 45 CFR 149.620(f)(1) states that at any point after the dispute resolution process has been initiated but before the date on which a determination is made by the SDR entity, the parties can settle the payment amount through either an offer of financial assistance or an offer to accept a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full.

In the event that the parties agree to settle on a payment amount, the provider or facility should notify the SDR entity through the Federal IDR Portal, electronically, or in paper form, as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date upon which settlement was reached, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must

also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount that is equal to at least half the amount of the administrative fee paid as discussed in section VI.B.8 of this preamble. Once the SDR entity receives the notification of the settlement, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

HHS also clarifies that payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount. For example, if the uninsured (or self-pay) individual has already made payment or entered into a payment plan and then chooses to enter dispute resolution, the fact that they previously paid, or agreed to pay, all or part of the billed charges may not be used by the provider or facility to prove that a settlement has been reached to avoid the patient-provider dispute resolution process.

HHS is of the view that providing an opportunity for the uninsured (or self-pay) individual and the provider or facility to come to terms on a payment amount that is mutually agreeable for the parties involved is appropriate as it may help resolve payment disputes quickly without the need for a determination by an SDR entity. Such a process can also incentivize a provider or facility to offer to accept a lower amount or to provide financial assistance to the uninsured (or self-pay) individual. However, HHS clarifies that neither party (the uninsured (or self-pay) individual or the provider or facility) is required to negotiate a settlement for the billed charges, and the decision to enter into a settlement on the payment amount is optional. In cases where there is no settlement, the SDR entity will make a determination as discussed in section VI.B.7.iii of this preamble.

HHS recognizes that to the extent that a provider or facility believes that a settlement may be more beneficial for them than the SDR entity determination, the provider or facility may be incentivized to seek a settlement. While such an outcome may be desirable in that it can lead to a quick resolution and could lead to provider or facility offering to accept a lower payment amount or other financial assistance to the uninsured (or self-pay) individual, HHS is concerned that the uninsured (or

self-pay) individual, particularly those without representation, would be at a disadvantage when negotiating with the provider or facility. HHS seeks comment on these concerns, including whether additional consumer protections should be considered, and ways HHS can increase an uninsured (or self-pay) individual's access to effective representation, through legal aid organizations or other groups.

ii. Determination of Payment Amount Through Patient-Provider Dispute Resolution

As part of the SDR determination process, 45 CFR 149.620(f)(2) requires that the health care provider or health care facility must submit information to the SDR entity not later than 10 business days after the receipt of the notice from the SDR entity initiating the patient-provider dispute resolution process described in section VI.B.4. This information must include: (1) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (2) a copy of the billed charges provided to the uninsured (or self-pay) individual for items or services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and (3) documentation demonstrating that the difference between the billed charges and the expected charges in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. While the statute does not specify what a provider or facility should provide to the SDR entity to inform the SDR entity's determination decision or how long a provider or facility should have to report such information, HHS is of the view that it is both necessary and appropriate to require the provider or facility to provide the copies of the bill and good faith estimate for the item or service in question as such information can be helpful for the SDR entity to verify the eligibility of the dispute in question. Although the uninsured (or self-pay) individual will provide a copy of the bill and good faith estimate, requiring the provider or facility to also provide the bill and good faith estimate will allow the SDR entity to verify the information in the bill and good faith estimate provided by the uninsured (or self-pay) individual and identify any

potential discrepancies. HHS believes it is also necessary and appropriate to provide a means for a provider or facility to submit documentation or an explanation to support the billed charges, such as information related to the patient's relevant medical history that is necessary to demonstrate that the item or service is medically necessary and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS is of the view that such documentation from the provider or facility would assist the SDR entity with making a fair assessment whether the billed charge is appropriate because otherwise the SDR entity would be unfamiliar with the facts that would allow the SDR entity to assess medical necessity, and whether the need for the items or services was foreseeable. The interim final rules require that this information be submitted within 10 business days, this time period is similar to the Federal IDR process requirements for submitting documentation to support a dispute resolution determination as outlined in PHS Act section 2799B-1. HHS is of the view that a 10-business-day time period is sufficient for a provider or facility to gather and submit the required information, as this information should be documented as part of the individual's patient record.

Not later than 30 business days after receipt of the information from the provider described in section 45 CFR 149.620(f)(2)(i), the SDR entity must make a determination on the amount to be paid by such uninsured (or self-pay) individual taking into account the requirements described in section VI.B.7.iii of this preamble. The 30-business day timeframe is also similar to the requirement in the Federal IDR process in PHS Act section 2799A-1(c)(5) where not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the item or service. HHS is of the view that 30 business days should provide sufficient time for an SDR entity to review the submitted information and issue a determination. The SDR entity is required to assess the information submitted by the provider or facility according to the requirements described in 45 CFR 149.620(f)(3) and discussed in section VI.B.7.iii of this preamble.

iii. Requirements for Determination

45 CFR 149.620(f)(3) sets forth the requirements for SDR entities in making

payment determinations. As described in section VI.A.3 of this preamble, the itemized list of items or services in a good faith estimate must reflect the expected charges from the convening provider or facility and items and services reasonably expected to be provided by co-providers or co-facilities and must be built upon accurate information that was known at the time the good faith estimate was given to the uninsured (or self-pay) individual. As a result, the SDR entity should use the expected charges in the good faith estimate as the presumed appropriate amount and unless the provider or facility provides credible information justifying the difference between the total billed charges and the good faith estimate by demonstrating that the difference between the billed charges and the expected charges in the good faith estimate for the item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. For this purpose, information is credible if upon critical analysis the information is worthy of belief and consists of trustworthy information. This is the same standard the Departments are adopting at 26 CFR 54.9816-8T, 29 CFR 2590.716-8, and 45 CFR 149.510 for the Federal IDR processes discussed in section III.D.4 of this preamble. HHS is of the view that maintaining a consistent standard of review among IDR entities and SDR entities, while still recognizing the inherent differences in the respective processes based on the applicable parties, minimizes program complexity and reduces the potential for confusion among providers and facilities over the applicable standards for review.

As stated previously, HHS acknowledges that unforeseen factors during the course of treatment could result in additional items or services furnished and could result in higher billed amounts after receipt of care than was anticipated at the time the good faith estimate was provided. HHS does not expect that the good faith estimate would include charges for unanticipated items or services that could occur due to unforeseen events. In cases where changes in the underlying circumstances occur during treatment and would reasonably result in higher than expected charges, the SDR entity may consider additional factors that support charges for medically necessary items or services. As information to demonstrate that the difference between

the billed charges and the expected charges for an item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, providers or facilities should provide documentation, which can include a written explanation, detailing any change in circumstances, how that change resulted in a higher billed charge than the expected charge for the item or service in the good faith estimate, and why the billed charge reflects the cost of a medically necessary item or service. HHS considered requiring the provider or facility to provide only evidence that the difference between the billed charges and the expected charges for the item or service in the good faith estimate reflects the costs of a medically necessary item or service, and not require the provider or facility demonstrate the item or service is based on unforeseen circumstance that could not have reasonably been anticipated when the good faith estimate was provided. However, HHS is of the view that an item or service that is medically necessary and could reasonably have been anticipated should already be included on the good faith estimate and without such information the uninsured (or self-pay) individual would not have been provided with an accurate estimate of the expected charges. HHS is of the view that not requiring the provider or facility to demonstrate that the item or service could not have been anticipated could incentivize a provider or facility to not list all items or services on the good faith estimate which could lead to less-accurate estimates provided to uninsured (or self-pay) individuals.

Uninsured (or self-pay) individuals may also submit additional documentation through the Federal IDR portal, although they are not required to provide documentation beyond the information included in the initiation notice, such as the good faith estimate and the billed charges.

The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual or their authorized representative, and a provider or facility, and must make a determination as to whether the provider or facility has provided credible information for each billed item or service to demonstrate that the difference between the billed charge and the expected charge in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could

not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. The SDR entity should make this determination separately for each unique billed item or service. HHS is of the view that this helps ensure that the SDR entity review is comprehensive and that the facts and circumstances for each billed charge are considered by the SDR entity. HHS is also of the view that this approach ensures that the uninsured (or self-pay) individual is only billed charges that reflect medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

For any item or service where the billed charge is equal to or less than the expected charge in the good faith estimate, the SDR entity will determine the payment amount to be the billed charge. If the billed charge is higher than the expected charge for an item or service in the good faith estimate and the SDR entity determines the provider or facility has not provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid by the uninsured (or self-pay) individual for the item or service to be equal to the expected charge for the item or service listed in the good faith estimate. If the SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid by the uninsured (or self-pay) individual to be the lesser of: (1) The billed charge; or (2) the median payment amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2), or if the amount reflected in the independent database is less than the expected charge in the

good faith estimate, the good faith estimate amount.

In cases in which the SDR entity determines that the provider or facility has provided credible information that difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, HHS considered whether to always require the SDR entity to set the payment amount equal to the billed charge. However, HHS is concerned that such an approach may increase the incentive for providers and facilities to inflate their billed charges, particularly in cases where the provider or facility believes they can justify the additional billed charge. Requiring the SDR entity to select as a payment amount the median payment amount for the same or similar item or service in a geographic area, if lower than the billed charge but higher than the expected charge in the good faith estimate, ensures that the uninsured (or self-pay) individual is protected from billed charges that are above the market rate for items or services provided. HHS acknowledges that under this approach an SDR entity can determine a payment amount lower than the original billed charge in circumstances where a provider or facility submits credible information justifying the additional item or service as reflecting a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS also recognizes that such an approach could increase the incentive for the uninsured (or self-pay) individual to initiate patient-provider dispute resolution even in cases where the uninsured (or self-pay) individual believes the extra billed charges to be justified. However, HHS is of the view that PHS Act section 2799B-7 establishes important consumer protections from unexpected billed charges that are substantially in excess of the expected charges in the good faith estimate, even in cases where the difference between the billed charge and the expected charges in the good faith estimate may reflect the costs of a medically necessary item or service and is based on unforeseen circumstances that could not reasonably be anticipated when the good faith estimate was provided. These protections ensure that the uninsured (or self-pay) individual is protected from excessive billed charges even

when such billed charges reflect a medically necessary item or service and are based on unforeseen circumstances that could not reasonably be anticipated when the good faith estimate was provided. In addition, HHS is of the view that the median payment amount is a reasonable payment amount, as the methodology was established to calculate a fair market rate for an item or service, and although this methodology was developed for group health plans and health insurance issuers offering group or individual health insurance coverage, it can also be leveraged to determine whether the billed charge is less than a fair market price, instead of creating separate standards regarding median rates as applied to the QPA and payment amounts applied to the patient provider dispute resolution process.

For new items or services not originally listed on the good faith estimate, if the SDR entity determines the provider or facility did not provide credible information that demonstrates that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity will determine a payment amount equal to \$0. HHS is of the view that PHS Act section 2799B-7 establishes consumer protections for uninsured (or self-pay) individuals in the event they receive surprise charges that are not reflected in the good faith estimate. HHS is of the view that requiring the uninsured (or self-pay) individual to pay for items or services they did not anticipate, absent a determination that such a billed charge is supported by credible information that the billed charge reflects a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, would run counter to the protections intended in PHS Act section 2799B-7. If the SDR entity determines that a provider or facility has provided credible information that the billed charge for new items or services that did not appear on the good faith estimate reflects the costs of a medically necessary item or service that is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine the charge to be paid by the uninsured (or self-pay)

individual for the new item or service as the lesser of two payment amounts: (1) The billed charge; or (2) the median payment amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2).

After making a determination for all items or services subject to patient-provider dispute resolution, the SDR entity must add together the amounts to be paid for all items and services. As further discussed in section VI.B.8 of this preamble, in cases in which the final amount determined by the SDR entity is lower than the total billed charges, the SDR entity must reduce the final amount by an amount equal to the administrative fee amount paid by the individual (to account for the administrative fee charged to the provider or facility) to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services subject to the SDR entity determination. HHS acknowledges that under this approach, particularly in cases where the provider or facility submits credible information to justify the additional billed charges, the SDR entity may still determine a lower payment amount than the billed charge and the provider or facility would end up paying an administrative fee in a large portion of patient-provider dispute resolution cases. However, HHS is of the view that the intent behind the consumer protections in PHS Act section 2799B-7 is to protect the uninsured (or self-pay) individual from unexpected billed charges that are substantially in excess of the expected charges in the good faith estimate, and as a result, the uninsured (or self-pay) individual should be held harmless in cases where the process results in a lower payment amount.

Once the final payment determination amount has been calculated, the SDR entity must inform the uninsured (or self-pay) individual and the provider or facility using the Federal IDR portal, and depending on the individual's or provider's or facility's preference, electronically or by paper mail, of such determination, along with the SDR entity's justification for making such a determination.

To provide an example of how the payment determination would operate in practice, consider a situation in which an uninsured (or self-pay) individual initiates the dispute resolution process against a provider for services A, B, C, and D. Services A and B were listed on the good faith estimate. The expected charge for service A was higher than the billed charge for service

A, the expected charge for service B was lower than the billed charge for service B, and services C and D were not included on the good faith estimate and are thus new services. The difference between the total of the billed charges for services A, B, C, and D and the total expected charges for services A and B (services C and D were new services and not included in the good faith estimate) was determined to be at least \$400 more than the amount listed in the good faith estimate, and thus these services were found to be eligible for patient-provider dispute resolution. When the SDR entity reviews the documentation submitted by the provider, because the billed charge for service A is less than the expected charge for service A, the SDR entity determines the amount to be paid to be equal the billed charge for service A. If the SDR entity determines the provider did not provide credible information that the difference between the higher billed charge and the expected charge for service B reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity determines the amount to be paid for service B to be equal to the expected charge for service B on the good faith estimate. If the SDR entity determines the provider did provide credible information that billed charges for services C and D reflects the costs of medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity would determine the amounts to be paid for services C and D. Due to services C and D being new services, and as a result not having a corresponding expected charges in the good faith estimate, the SDR entity shall determine the payment amounts for services C and D to be the lesser of: (1) The billed charge; or (2) the median payment amount for the same or similar service in that geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2) (had expected charges for services C or D been included in the good faith estimate, the median payment amount for the same or similar service in that geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2) should not be considered if less than the expected charges for the services

contained in the good faith estimate). The SDR entity would then add together all the payment amounts determined for services A, B, C, and D. Due to the uninsured (or self-pay) individual's payment amount being determined to be lower than the initial billed charge, the SDR entity adjusts the final determination amount to reduce it by an amount equal to the uninsured (or self-pay) individual's administrative fee payment, to calculate the final determination amount. The SDR entity then notifies the uninsured (or self-pay) individual and the provider of the determination, the determination amount, and the reasons for the determination and closes the case.

In determining the median payment amount from an independent database, the requirements and methodology set forth in 45 CFR 149.140(c)(3) apply. HHS is of the view that utilizing the same methodology for the calculation of median rates for the QPA, when a plan or issuer does not have sufficient internal information to calculate the QPA, as the methodology for calculating the median payment amounts under the patient-provider dispute resolution process is reasonable and appropriate. This approach will allow an equivalent standard to be applied across multiple instances where the regulation refers to median rates, and will reduce confusion that may result from conflicting standards or definitions. HHS is of the view that creating a separate methodology specifically for the calculation of median payment amounts, using an independent database, as they pertain to the patient-provider dispute resolution process is unnecessary and therefore SDR entities must use this methodology when determining a median payment amount. HHS seeks comment on this methodology as a reasonable way to calculate median payment amounts for purposes of the patient-provider dispute resolution process.

HHS considered whether to allow the SDR entity to have discretion to determine a payment amount lower than the expected charges in the good faith estimate. However, HHS is of the view that such an approach would result in less transparency and predictability for the uninsured (or self-pay) individuals, providers, and facilities regarding the outcome of the patient-provider dispute resolution process. PHS Act sections 2799B-6 and 2799B-7 establishes a backstop for an uninsured (or self-pay) individual that protects them from unexpected bills that substantially exceed the expected charges in the good faith estimate. Given that the provider or facility is required

to provide the uninsured (or self-pay) individual with a good faith estimate upon scheduling or upon request prior to furnishing the items or services to the individual. HHS is of the view that the good faith estimate represents charges the uninsured (or self-pay) individual would likely expect to pay for the items or services. Therefore, the good faith estimate represents an appropriate amount to be determined as the payment amount when the uninsured (or self-pay) individual prevails. Additionally, setting the payment amount equal to the good faith estimate protects the uninsured (or self-pay) individual from unexpected billed charges in cases where the extra charges do not reflect the costs of a medically necessary item or service that is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided while providing predictability to uninsured (or self-pay) individuals, providers and facilities on what to expect from the patient-provider dispute resolution process. However, HHS recognizes that such an approach may encourage providers or facilities to be overinclusive regarding the list of expected charges in the good faith estimate, thus leading to higher good faith estimates than they otherwise would have provided.

HHS seeks comment on the approach for the determination of payment amounts by the SDR entity, including the feasibility of the approach, as well as comment on alternative approaches. HHS also seeks comment on ways to reduce the incentives for providers and facilities to over include items or services on the good faith estimate, and the circumstances, if any, in which requiring the SDR entity to set a payment amount below the expected charges in the good faith estimate would be appropriate. HHS also seeks comment on the use of the median amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2), including comment on the feasibility of such an approach, and comment on whether a different methodology should also be considered.

iv. Effects of Determination

Under the Federal IDR process established in PHS Act sections 2799A-1(c)(5)(E) and 2799A-2(c)(5)(D), determinations made by a certified IDR entity are binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity

involved. PHS Act section 2799B-7 establishes a separate dispute resolution process to determine payment amounts made to a provider or facility by an uninsured (or self-pay) individual when the uninsured (or self-pay) individual is billed charges substantially in excess of the expected charges in the good faith estimate; however, the statute is silent regarding the effects of such determinations. HHS is of the view that it is both necessary and appropriate to similarly require that determinations made by SDR entities be binding upon all parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the SDR entity involved regarding such claim. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary and appropriate in order to implement the provisions of PHS Act section 2799B-7 to ensure the consumer protections established under PHS Act section 2799B-7 operate as intended. Without making the determination binding, the consumer protections established in PHS Act section 2799B-7 would be significantly diminished and the cost for administering the program may outweigh the benefits. Therefore, under 45 CFR 149.620(f)(4), a determination made by an SDR entity will be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the SDR entity regarding such claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, or the individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount. HHS seeks comment on the approach regarding SDR entity determinations being binding, including the feasibility of such approach, as well comment on alternative approaches. HHS also seeks comment on subject of judicial review. PHS Act section 2799A-1(c)(5)(E) requires that determinations not be subject to judicial review, except in a case described in any paragraphs (1) through (4) of section 10(a) of title 9, United States Code. HHS seeks comment on the feasibility or desirability of adopting a similar application for the patient-provider dispute resolution process, as well as comment on alternative approaches.

8. Costs of Patient-Provider Dispute Resolution Process

PHS Act section 2799B-7, as added by the No Surprises Act, directs the

Secretary of HHS to establish an administrative fee “to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual’s access to such process.” Aside from the administrative fee, discussed later in this section, the No Surprises Act does not specifically address requirements for how the costs for the SDR entity to conduct patient-provider dispute resolution determinations (dispute resolution costs) should be funded.

HHS considered various approaches with respect to how the dispute resolution costs should be treated for the patient-provider dispute resolution process. HHS recognizes that it is important for the SDR entity to be appropriately compensated for providing patient-provider dispute resolution services. HHS considered maintaining a similar fee structure as in the Federal IDR process where the non-prevailing party would be required to pay all the costs of the IDR entity. However, HHS is of the view that requiring an uninsured (or self-pay) individual to pay the entire dispute resolution costs in cases where the provider or facility prevails in the dispute resolution process could be prohibitive for individuals to access the dispute resolution process. HHS is also concerned that requiring a provider or facility to pay dispute resolution costs when they do not prevail could impose a burden on the provider or facility and potentially provide an incentive for the provider or facility to raise prices for uninsured (or self-pay) individuals to account for potential dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether.

HHS is also of the view that while the patient-provider dispute resolution process is similar to the Federal IDR process in several important ways, the patient-provider dispute resolution process does have unique distinctions. In particular, while in the Federal IDR process, both the providers (and providers of air ambulance services) and the payers can initiate the IDR process, and both parties have an incentive to resolve the dispute, in the patient-provider dispute resolution process only the uninsured (or self-pay) individual can initiate the dispute resolution process, and HHS is concerned that the provider or facility would not have the same incentive to participate in the dispute resolution process as the uninsured (or self-pay) individual. Similarly, there will likely be a significant imbalance in both power and knowledge between the provider or facility and the uninsured (or self-pay)

individual initiating the dispute resolution process. As a result, HHS is of the view that a different approach to dispute resolution costs is needed for the patient-provider dispute resolution process. As a result, HHS determined that an approach where HHS would pay dispute resolution costs by directly contracting with SDR entities is the appropriate approach, as it would address the concerns discussed earlier in this section of the preamble. HHS is also of the view that such an approach will streamline the patient-provider dispute resolution process and minimize potential burdens on uninsured (or self-pay) individuals, and providers and facilities.

HHS is adopting an approach for the patient-provider dispute-resolution process in which HHS will pay dispute resolution costs through contracts with SDR entities. Such an approach ensures that the uninsured (or self-pay) individual would not be required to pay dispute resolution costs, and as a result, such costs would not pose a barrier to accessing the dispute resolution process. Adopting such an approach in which HHS pays the dispute resolution costs would minimize the burdens placed on uninsured (or self-pay) individuals and on providers or facilities, and reduce the incentives for providers and facilities to increase prices or restrict an uninsured (or self-pay) individual’s access to needed care. Adopting an approach where the individual would not be required to bear the dispute resolution costs would help ensure that such costs would not be a barrier to the uninsured (or self-pay) individual’s access to the dispute resolution process.

Aside from dispute resolution costs, PHS Act section 2799B–7 requires that the Secretary of HHS establish an administrative fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual to participate in such process. HHS is aware that not requiring the uninsured (or self-pay) individual to pay dispute resolution costs could lead to overutilization of the patient-provider dispute resolution process; however, this concern is mitigated by limiting the availability of the patient-provider dispute resolution only to cases where the total billed charge for items or services per provider or facility are billed in excess of the expected charges by at least \$400 more than the amount listed in the good faith estimate, as discussed in section VI.B.2 of this preamble. In addition, HHS is of the view that requiring parties to the dispute resolution process to pay an

administrative fee to offset some of the Federal costs for implementing the patient-provider dispute resolution program is appropriate. Such a requirement is also similar to the Federal IDR process, which requires all parties to pay an administrative fee to cover Federal costs; however, under that process, the fee is required to equal the estimated costs to the Federal Government, while in the patient-provider dispute resolution process the administrative fee is required to be established so that it would not create a burden for the uninsured (or self-pay) individual to participate in the dispute resolution process.

HHS intends to assess an administrative fee on the non-prevailing party (providers, facilities, and uninsured (or self-pay) individuals) to the patient-provider dispute resolution process. For purposes of the patient-provider dispute resolution process, the prevailing party means the provider or facility when the SDR entity determines the total amount to be paid to be equal to the total billed charges, whereas the prevailing party means the uninsured (or self-pay) individual when the SDR entity determines the total amount to be paid to be less than the total billed charges. Upon the SDR entity determination, if the uninsured (or self-pay) individual is the prevailing party, the SDR entity would apply a reduction, equal to the administrative fee amount paid by the individual, to the final determination amount to be paid by the individual for the items or services. HHS is of the view that requiring the non-prevailing party to pay the entire administrative fee (either in a payment made directly to the SDR entity in the case of the uninsured (or self-pay) individual, or in a reduction in the final payment determination amount as in the case of the provider or facility) ensures that both parties are treated the same with regards to the administrative fee assessed. Additionally, requiring only the non-prevailing party to pay the administrative fee will help ensure that the party that prevails in dispute resolution is not penalized for participating in the process. Under this approach, the uninsured (or self-pay) individual who is the initiating party in the patient-provider dispute resolution process will pay the administrative fee at the process initiation through the SDR entity. HHS is of the view that since the uninsured (or self-pay) individual is the initiating party, waiting for the provider or facility to submit the administrative fee prior to the SDR entity making a determination may result in undue delays to the

process. In cases in which the uninsured (or self-pay) individual prevails in dispute resolution, the SDR entity would apply a reduction equal to the administrative fee paid by the individual to the final determination amount to be paid by the individual for the items or services. HHS is of the view that requiring the provider or facility to pay the administrative fee to the uninsured (or self-pay) individual through a reduction in the final determination amount to be paid is the appropriate approach as it simplifies the number of transactions, rather than requiring the provider or facility to provide a payment directly to the SDR entity. This approach also ensures that in cases in which the uninsured (or self-pay) individual prevails, the SDR entity will reduce the amount the uninsured (or self-pay) individual ultimately is required to pay for an item or services by the amount of the administrative fee paid so that it is not left to the provider or facility to apply the reduction equal to the administrative fee paid to the final payment amount. In cases where the provider or facility prevails in dispute resolution, the SDR entity would not reduce the final payment amount by an amount equal to the amount of the administrative fee paid by the uninsured (or self-pay) individual.

In cases described in section VI.B.7.i of this preamble where the parties to dispute resolution agree to settle the payment amount prior to the SDR entity making a determination, both parties will be responsible for paying half the amount of the administrative fee. In this case, the provider or facility will document in the settlement notice described in section VI.B.7.i of this preamble that it has reduced the settlement amount by at least half of the administrative fee amount paid by the uninsured (or self-pay) individual.

HHS intends to establish an administrative fee in guidance in a manner that will not create a barrier to an uninsured (or self-pay) individual's access to the patient-provider dispute resolution process. In setting the fee HHS is considering expected costs to HHS for operating the patient-provider dispute resolution program, including contractor costs, and costs to HHS for utilizing the Federal IDR portal for patient provider dispute resolution cases. However, due to the requirements in PHS Act section 2799B-7 that such administrative fee must not pose a burden to participate for uninsured (or self-pay) individual to participate in the patient-provider dispute resolution process, HHS is of the view that it is necessary and appropriate to limit the size of the administrative fee. As a

result, HHS expects the fee to be no more than \$25, which HHS believes would allow HHS to offset some of the costs of operating the dispute resolution process while keeping the administrative fee low enough to ensure uninsured (or self-pay) individuals are able to access the dispute resolution process. HHS considered whether to base the administrative fee on annual household income but is concerned that such an approach would require an uninsured (or self-pay) individual to submit financial documentation to verify their income which could significantly increase complexity to initiate the dispute resolution process and could create additional burdens for an uninsured (or self-pay) individual to participate. HHS intends to evaluate patient-provider dispute resolution case volume, contract costs, and other Federal costs for the program and may adjust this fee in subsequent years through guidance to ensure that the fee continues to mitigate overutilization of the patient-provider dispute resolution process, offsets some of HHS's costs of operating the dispute resolution process, and also does not pose a burden for uninsured (or self-pay) individuals regarding participation in the process. HHS seeks comment on this approach, including comment on whether the administrative fee should be higher or lower, the feasibility of the approach to collecting the administrative fee, including comment on alternative approaches that HHS should consider. HHS also seeks comment on ways to ensure public awareness of the dispute resolution process, including the administrative fee and how payments are handled, as well as comment on potential unintended or disparate impacts of administrative costs on underserved and underrepresented populations.

9. Deferral to State Patient-Provider Dispute Resolution Processes

The No Surprises Act establishes strong consumer protections for uninsured (or self-pay) individuals to have access to the patient-provider dispute resolution process in cases in which billed charges substantially exceed expected charges in the good faith estimate. HHS is of the view that PHS Act section 2799B-7 operates in such a way that all uninsured (or self-pay) individuals, regardless of state, are required to have at least the minimum protections set forth in the statute. However, HHS has considered circumstances where states may wish to develop their own processes for resolving disputes between uninsured (or self-pay) individuals and providers

or facilities. HHS is of the view that when a state law is in effect that provides a process for resolving disputes between an uninsured (or self-pay) individual and a provider or facility that meets or exceeds the consumer protections contained in PHS Act section 2799B-7, such a process should continue to apply. In addition, HHS believes that such an approach is consistent with other provisions of the No Surprises Act such as allowing the application of a state law established to determine the total amount payable under such a plan, coverage, or issuer for certain emergency services. HHS is adding new 45 CFR 149.620(h) to establish a process by which HHS will determine whether a state patient-provider dispute resolution process provides at least the same level of consumer protections as does the Federal process. HHS will communicate with the state and determine whether a state law provides for such a dispute resolution process, and ensure that such process meets or exceeds certain minimum Federal requirements. If HHS determines that the state has in effect a state law that meets or exceeds the minimum Federal requirements, then HHS will defer to the state process. In such case the patient-provider dispute resolution process operated by HHS will not be available in that state. As further discussed in section VI.B.5 of this preamble, as part of the contracting and certification process for an SDR entity, the entity must demonstrate the ability to operate nationwide, including the ability to operate in states where a state process is terminated so that uninsured (or self-pay) individuals continue to have access to a process that meets Federal standards. HHS will direct any patient-provider dispute resolution requests received by HHS from uninsured (or self-pay) individuals in that state to the state process to adjudicate the dispute resolution initiation request according to the state process. HHS will assess such state process for compliance with the minimum Federal standards to ensure any such state process includes the same or greater level of consumer protection as would apply under the Federal patient-provider dispute resolution process. If HHS determines that such state process meets or exceeds the minimum Federal standards, HHS will discuss such determination with the state as well as notify the state in writing of such determination.

HHS considered what minimum requirements a state law must include in order for HHS to determine that the state's law is at least as consumer

protective as the protections contained in the No Surprises Act. At a minimum, the state process should: (1) Be binding, unless the provider or facility offers for the uninsured (or self-pay) individual to pay lower amount than the determination amount; (2) take into consideration a good faith estimate, that meets the minimum standards established under 45 CFR 149.610, provided by the provider or facility to the uninsured (or self-pay) individual; (3) have a fee to participate in the patient-provider dispute resolution process that is equal to or lower than the Federal administrative fee; and (4) have in place conflict-of-interest standards that at a minimum meet the requirements set forth in 45 CFR 149.620(d) and (e)(3).

In order to ensure that a state process continues to meet or exceed the consumer protections contained in the No Surprises Act, HHS will review changes to the state process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards. HHS is of the view that having a process to reassess state dispute resolution processes is important for ensuring that uninsured (or self-pay) individuals receive at least the same level of protection as the Federal standard. In the event that the state process is terminated, or HHS determines that it no longer meets the minimum Federal requirements, HHS will make the Federal process available to ensure that ensures the state's residents have access to a dispute resolution process that meets the minimum Federal requirements.

Although the Federal process will be available for uninsured (or self-pay) individuals except in states where HHS has made a determination that the state has established a State process that includes the same or greater level of consumer protection as would apply under the Federal process, HHS recognizes that some states may have in place other programs that seek to resolve payment disputes between uninsured (or self-pay) individuals and providers or facilities that do not meet the minimum Federal standards and thus would not take the place of the Federal dispute resolution process. However, HHS notes that nothing would prevent the uninsured (or self-pay) individual from voluntarily choosing to use such state programs to resolve a payment dispute instead of utilizing the Federal dispute resolution process. HHS

seeks comment on the approach to allow the HHS to defer to a state established patient-provider dispute resolution process that meets certain minimum Federal standards, including the feasibility and appropriateness of such approach, and whether additional minimum Federal standards should be considered.

10. Extension of Time Periods for Extenuating Circumstances

Similar to the provisions set forth in section III.D.8 in this preamble for the Federal IDR process under Code section 9816(c)(9), ERISA section 716(c)(9), PHS Act section 2799A-1(c)(9), and codified at 26 CFR 54.9816-8T(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g), the time periods specified in these interim final rules (other than the time for payment of the administrative fees discussed in section VI.B.4 of this preamble) may be extended in the case of extenuating circumstances at HHS' discretion on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by individuals, providers, and facilities to comply with the terms of these interim final rules. Additionally, for the extension to be granted, the parties must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable. The parties may request an extension by submitting a request for an extension due to extenuating circumstances, such as a natural disaster or other circumstances impeding efforts to comply with the terms of these interim final rules, through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

11. Applicability of the Patient-Provider Dispute Resolution Process

The provisions in PHS Act section 2799B-7 require the patient-provider dispute resolution process to be established by the Secretary of HHS no later than January 1, 2022. Consistent with this statutory provision, the requirements under 45 CFR 149.620 are applicable to uninsured (or self-pay) individuals; providers, facilities, and providers of air ambulance services; and SDR entities, beginning on or after January 1, 2022. The interim final rules regarding SDR entity certification at 45 CFR 149.620(a) and 45 CFR 149.620(d), are applicable beginning on October 7, 2021 so that HHS can begin certifying

SDR entities before the patient-provider dispute resolution process becomes applicable.

VII. Waiver of Proposed Rulemaking

Code section 9833, ERISA section 734, and PHS Act section 2792 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.

Under the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*), a general notice of proposed rulemaking is not required when an agency for good cause finds 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. 5 U.S.C. 553(b)(B). In addition, section 553(d) ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Finally, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

The Secretaries and the 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 a full public notice and comment process has been completed and find that there is good cause to waive the delay in effective date for certain provisions of these interim final rules.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act, 2021. The IDR and internal claims appeals and external review provisions generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The provisions related to protections for the uninsured generally apply beginning on 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. The provisions related to the certification of IDR and SDR entities, as described in the Applicability Dates section of this final rule, apply beginning October 7, 2021.

These interim final rules require plans, issuers, providers, facilities, and providers of air ambulance services to follow a certain process in determining out-of-network payment amounts for certain specified services. These regulations are intended to work in concert with the protections against surprise billing already instituted in the July 2021 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 premium or contribution rates and in making other changes to benefit designs. In some cases, issuers will need time to secure approval for required changes in advance of plan or policy years.

These interim final rules also set up certification requirements for IDR entities and requirements to which they must adhere in selecting payment offers. IDR entities will need time to acquire the necessary expertise and evidence of qualification to apply for certification in order to be prepared to conduct payment determinations for plan years beginning on or after January 1, 2022.

The Departments and OPM anticipate that 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, will allow plans and issuers to account for the regulations as they finalize rates and plan offerings and will allow IDR entities to seek certification and be available to take part in the Federal IDR process when these interim final rules go into effect.

Health plans and issuers, and providers, facilities and providers of air ambulance services, require these rules to be in place to determine the out-of-network rates for emergency services, services by out-of-network providers at in-network facilities in certain circumstances, and air ambulance services. Without these final rules, providers, facilities and providers of air ambulance services will not be able to resort to the Federal IDR process (and are no longer able to balance bill patients), leaving the possibility that they will be undercompensated for their

services. Such undercompensation could threaten the viability of these providers, facilities and providers of air ambulance services. This in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care, undermining the goals of the No Surprises Act. Additionally, and for the same reasons, the failure to promulgate this rule in a timely fashion could lead to additional industry consolidation, potentially driving health costs higher.

The Departments considered whether they could exercise enforcement discretion while a rule was proposed and then finalized. However, the No Surprises Act requires that the government set up and administer a Federal IDR process to determine out-of-network rates. Therefore, the Department must establish set rules for this process, including for the certification of certified IDR entities, in order that certified IDR entities, rather than the Departments, may determine out-of-network rates as contemplated by the No Surprises Act.

These interim final rules place new requirements on providers, facilities and providers of air ambulance services regarding how they must initiate open negotiation and the Federal IDR process, as well as what information they must provide to certified IDR entities when engaging in the Federal IDR process. Providers, facilities, and providers of air ambulance services require time to implement these new requirements to ensure compliance by January 1, 2022.

In addition to the requirements for the Federal IDR process, these interim final rules require providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, or a Federal health care program, and if enrolled in such plan or coverage, if the individual is seeking to have a claim for such item or service submitted to such plan or coverage. In the case that the individual is enrolled in such a plan or coverage (and is seeking to have a claim for such an item or services submitted to such plan or coverage), PHS Act section 2799B–6 requires that the provider or facility furnish the good faith estimate to the individual's plan or the issuer of the coverage to inform the advanced explanation of benefits that plans and issuers are required to provide a participant, beneficiary or enrollee under PHS section 2799A–1(f), Code section 9816(f), and ERISA section

716(f).⁹⁹ In the case that the individual requesting or scheduling a good faith estimate for an item or service is uninsured (or self-pay), these interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the individual. Providers and facilities will need time to implement requirements for furnishing good faith estimates to uninsured (or self-pay) individuals and time to develop processes for sharing and receiving information required for the good faith estimate with co-providers and co-facilities. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking, should allow providers and facilities to account for the regulations as they implement requirements to inquire about an individual's enrollment in

⁹⁹ As stated in the August 20, 2021 FAQs issued by the Departments, the Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers starting January 1, 2022 the good faith estimates required under PHS Act section 2799B–6, which plans and issuers must then include in the advanced explanation of benefits. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Additionally, stakeholders have requested that the Departments delay the applicability date of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with these sections is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement these provisions, including establishing appropriate data transfer standards. Until that time, the Departments will defer enforcement of the requirement that plans and issuers must provide an advanced explanation of benefits. HHS will investigate whether additional interim solutions for insured consumers are feasible. The Departments note that any rulemaking to fully implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6(2)(A) will include a prospective applicability date that provides plans, issuers, providers, facilities, and providers of air ambulance services with a reasonable amount of time to comply with new requirements. HHS encourages states that are primary enforcers of these requirements with regard to providers and issuers to take a similar enforcement approach, and will not determine that a state is failing to substantially enforce these requirements if it takes such an approach. See FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf> and <https://www.hhs.gov/guidance/document/faqs-about-affordable-care-act-and-consolidated-appropriations-act-2021-implementation>.

health care coverage and to furnish a good faith estimate to an uninsured (or self-pay) individual when these interim final rules goes into effect.

These interim final rules provide further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (patient-provider dispute resolution) under which an uninsured (or self-pay) individual may seek a determination from a certified dispute resolution entity for billed charges in excess of the good faith estimate. These interim final rules also place new requirements on uninsured (or self-pay) individuals, and providers or facilities regarding how they must initiate patient-provider dispute resolution, what information they must provide to dispute resolution entities for the dispute resolution process, and costs associated with patient-provider dispute resolution. Similar to the Federal IDR process, these interim final rules also establish certification requirements for SDR entities and requirements to which they must adhere in determining payment amounts. SDR entities will need time to acquire the necessary expertise, and enter into a contract with HHS to provide patient-provider dispute resolution. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking and waiving the delay in effective date for the provisions related to SDR certification will allow SDR entities to account for the regulations as they seek to contract with HHS and be available for patient-provider dispute resolution determinations when the related provisions in these interim final rules go into effect. Further, uninsured (or self-pay) individuals, providers, and facilities will need to understand what is required of them to engage in the patient-provider dispute resolution process when the interim final rules go into effect.

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 these interim final rules become effective, and that it is in the public interest to promulgate interim final rules. Further, for the same reasons as authorized by section 808(2) of the CRA, the Departments find it is impracticable and contrary to the public interest not to waive the delay in effective date for certain provisions of this IFC under section 801 of the CRA. Therefore, the Departments find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA and establish certain policies in this IFC

applicable as of the date of display at the Office of the Federal Register.

VIII. Economic Impact and Paperwork Burden

A. Summary

The Departments and OPM 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 Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, “significant” regulatory actions are subject to review by OMB. Section 3(f) of the Executive Order 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, 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. Based on the Departments’ estimates, OMB’s Office of Information and Regulatory Affairs has determined

this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).

Accordingly, the Departments have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of this rulemaking.

1.1. Need for Regulation

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 or facility that, generally unbeknownst to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual’s coverage. In the context of this discussion, medical services include air ambulance services. Surprise bills usually occur in situations where a patient is unable to choose a health care provider, emergency facility, or provider of air ambulance services. When they are unable to choose, they are unable to ensure they only receive care from providers or emergency facilities participating in their plan’s or coverage’s network.

Surprise bills can cause significant financial hardship and cause individuals to forgo care. 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.¹⁰⁰ A project carried out by Vox, a news and opinion website, which collected emergency department medical bills reported instances of accident victims who received care at out-of-network hospitals and received bills of over \$20,000.¹⁰¹ 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

¹⁰⁰ Pollitz K., et al., US Statistics on Surprise Medical Billing. JAMA. 2020;323(6):498. doi:10.1001/jama.2020.0065.

¹⁰¹ 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.

populations.¹⁰² Communities experiencing poverty and other social risk factors are particularly impacted as surprise medical bills can negatively affect consumers' abilities to eliminate debt and create wealth, and ultimately can impact a family for generations.¹⁰³ 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.¹⁰⁴

It has become common practice in the health care system for plans, issuers, and FEHB carriers to negotiate with health care providers. Plans, issuers, and FEHB carriers offer preference to these providers by listing them as "in-network providers," and in return, providers charge discounted rates to the plans, issuers, and FEHB carriers.¹⁰⁵ Joining a plan's, issuer's, or FEHB carrier's network assures providers of patient volume in exchange for lower reimbursements. However, for specialties for which consumers typically do not shop, such as services rendered by emergency departments,

patient volume does not depend on whether specific providers are in-network.¹⁰⁶ There is less of an incentive for these providers to engage in negotiations with plans, issuers, and FEHB carriers.¹⁰⁷ One study looked at claims data from a large commercial issuer for the period 2010–2016 and found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill.¹⁰⁸

Since the passage of the Emergency Medical Treatment and Labor Act (EMTALA) in 1986, Medicare-participating hospitals are required to provide emergency services, regardless of patients' abilities to pay.¹⁰⁹ Because of emergency physicians' legal obligation under EMTALA, and the inability of patients to make treatment decisions, including by selecting providers, in emergency settings, there are fewer incentives for emergency providers to contract with issuers.¹¹⁰ A large portion of emergency providers' costs are distributed to patients with health benefits, providing justification for plans, issuers, and FEHB carriers to offer smaller networks. Consequently, in recent years, plans, issuers, and FEHB carriers have been offering narrower networks alongside larger discounts, resulting in lower premiums but with fewer in-network options for consumers.¹¹¹

An additional factor contributing to the current environment is the increasing participation of private equity groups in the health care market through the acquisition of physician groups.¹¹² Anesthesiology, emergency medicine, family practice, and dermatology were the most common medical specialties in acquired physician groups.¹¹³ The private equity business model often centers on risky investments with short-term horizons. These firms often take on large amounts of debt to acquire an asset, then introduce structural and operational changes to extract value or increase revenue growth potential in the aim of selling the asset for a higher valuation.¹¹⁴ These firms often take on legally complex governance structures designed to protect the private equity firms from regulatory liability.¹¹⁵ By 2013, two private equity firms accounted for 30 percent of the physician staffing market.¹¹⁶ One study found that in 2017, hospitals acquired by private equity groups accounted for 7.5 percent of all nongovernmental hospitals and 11 percent of all discharges from nongovernmental hospitals.¹¹⁷ Private equity groups are also involved in air ambulance transport services. In 2018, two of the three

cato.org/files/2019-10/regulation-v42n3-1-updated.pdf. See also Polsky, D, Cidav Z., Swanson A. "Marketplace Plans With Narrow Physician Networks Feature Lower Monthly Premiums Than Plans With Larger Networks." *Health Affairs*. (October 2016). <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0693>.

¹¹² Zhu, Jane M., Lynn M. Hua, and Daniel Polsky. "Private Equity Acquisitions of Physician Medical Groups across Specialties, 2013–2016." *323 JAMA* 7 (2020): 663–665.

¹¹³ Zhu, Jane M., Lynn M. Hua, and Daniel Polsky. "Private Equity Acquisitions of Physician Medical Groups across Specialties, 2013–2016." *323 JAMA* 7 (2020): 663–665.

¹¹⁴ Konda S, Francis J, Motaparathi K, Grant-Kels JMGroup for Research of Corporatization and Private Equity in Dermatology. "Future Considerations for Clinical Dermatology in the Setting of 21st Century American Policy Reform: Corporatization and the Rise of Private Equity in Dermatology." *Journal of the American Academy of Dermatology*, 2019;81(1):287–296.e8. [https://www.jaad.org/article/S0190-9622\(18\)32667-7/fulltext](https://www.jaad.org/article/S0190-9622(18)32667-7/fulltext).

¹¹⁵ Appelbaum E, Batt R. "Private Equity Buyouts in Healthcare: Who Wins, Who Loses?" Institute for New Economic Thinking. (March 2020). <https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses>.

¹¹⁶ Appelbaum E, Batt R. "Private Equity Buyouts in Healthcare: Who Wins, Who Loses?" Institute for New Economic Thinking. (March 2020). <https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses>.

¹¹⁷ Offodile II, Anaeze C., et al. "Private Equity Investments in Health Care: An Overview of Hospital and Health System Leveraged Buyouts, 2003–17." *Health Affairs*, Vol. 40(5), (May 2021). <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01535>.

¹⁰² Butler S., Sheriff 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-Muniz 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>.

¹⁰³ 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/>.

¹⁰⁴ 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 health care for underserved populations. *MedCity News* (February 22, 2021). <https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/>.

¹⁰⁵ Greaney, Thomas. "Surprise Billing: a Window into the U.S. Health Care System." American Bar Association. (September 2020). https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/#:~:text=The%20E2%80%9Csurprise%20occurs%20when,the%20difference%20between%20what%20the

¹⁰⁶ Cooper, Z. et al. "Surprise! Out-of-Network Billing for Emergency Care in the United States." National Bureau of Economic Research: Working Paper 23623 (July 2017). <https://www.nber.org/papers/w23623>.

¹⁰⁷ Greaney, Thomas. "Surprise Billing: a Window into the U.S. Health Care System." American Bar Association. (September 2020). https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/#:~:text=The%20E2%80%9Csurprise%20occurs%20when,the%20difference%20between%20what%20the

¹⁰⁸ 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.

¹⁰⁹ Centers for Medicare and Medicaid Services. "Emergency Medical Treatment & Labor Act (EMTALA)." (March 2021). <https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA#:~:text=In%201986%2C%20Congress%20enacted%20the,regardless%20of%20ability%20to%20pay>.

¹¹⁰ Brannon, Ike and David Kemp. "The Potential Pitfalls of Combatting Surprise Billing." CATO Institute. (Fall 2019). <https://www.cato.org/sites/cato.org/files/2019-10/regulation-v42n3-1-updated.pdf>.

¹¹¹ Brannon, Ike and David Kemp. "The Potential Pitfalls of Combatting Surprise Billing." CATO Institute. (Fall 2019). <https://www.cato.org/sites/>

largest air ambulance transport companies were owned by private equity firms.¹¹⁸

In addition, some private equity firms may choose not to participate in plans' and issuers' networks in order to reap higher payments.¹¹⁹ Private equity-owned hospitals have been found to charge higher prices.¹²⁰ According to one study, 204 private equity-owned hospitals had an annual net income averaging \$8.5 million prior to their acquisition. After private equity groups purchased the hospitals, their net income rose to \$12.9 million.¹²¹ This represents a 52 percent increase in net income, on average. Another study found that the entry of two private equity firms into the hospital sector increased out-of-network billing rates by more than 30 and 80 percentage points, respectively, from 2011 to 2015.¹²² The study also found that the payments that one private equity firm received for emergency department physicians from insurers increased by 122 percent and patient cost-sharing payments to emergency department (ED) physicians increased by 83 percent. Furthermore, some hospitals and providers do not accept private health insurance coverage. For example, one study found that 5 percent of physicians participated in cash-only practices in 2020.¹²³ When billing out-of-network, these providers who choose to remain out-of-network can charge much higher fees than what public or private payers typically allow.¹²⁴

The Departments and OPM seek comment on how private equity

¹¹⁸ Appelbaum E, Batt R. "Private equity buyouts in healthcare: Who wins, who loses?" Institute for New Economic Thinking. (March 2020). <https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses>.

¹¹⁹ Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. "Surprise! Out-Of-Network Billing for Emergency Care in the United States." 128 *Journal of Political Economy* 9. (2020).

¹²⁰ Bruch, Joseph D., Suhas Gondi, and Zirui Song. "Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition." 180 *JAMA Internal Medicine* 11 (2020): 1428–1435.

¹²¹ Bruch, Joseph D., Suhas Gondi, and Zirui Song. "Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition." 180 *JAMA Internal Medicine* 11 (2020): 1428–1435.

¹²² Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. "Surprise! Out-Of-Network Billing for Emergency Care in the United States." 128 *Journal of Political Economy* 9. (2020).

¹²³ Oliver, Eric. "What Percent Of Physicians are in a Cash-Only Practice?—9 Stats." *Becker's ASC Review* (2021). <https://www.beckersasc.com/benchmarking/what-percent-of-physicians-are-in-a-cash-only-practice-9-stats.html>.

¹²⁴ Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. "Surprise! Out-Of-Network Billing for Emergency Care in the United States." 128 *Journal of Political Economy* 9. (2020).

ownership structures may be affected by the Federal IDR process.

Surprise billing represents a market failure, as often patients either do not have the option to seek care elsewhere or must make decisions based on incomplete information about the network status of providers and associated costs.¹²⁵ This market failure is exacerbated by the fact that patients must rely on the guidance of the provider, insurer, or plan, which have financial incentives that can be contrary to the patient's financial interests.¹²⁶

As of February 28, 2021, 18 states had implemented comprehensive legislation¹²⁷ regulating surprise billing, 15 states had implemented limited legislation, and 14 states had implemented an IDR system regarding out-of-network payments.¹²⁸ However, even in states that have passed legislation, states cannot regulate health plans that are self-insured by employers.¹²⁹

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.¹³⁰ 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. The No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual

¹²⁵ Assistant Secretary for Planning and Evaluation. "HHS Secretary's Report on: Addressing Surprise Medical Billing." Office of Health Policy. (July 2020). <https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf>.

¹²⁶ Assistant Secretary for Planning and Evaluation. "HHS Secretary's Report on: Addressing Surprise Medical Billing." Office of Health Policy. (July 2020). <https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf>.

¹²⁷ The states that have passed comprehensive legislation include California, Colorado, Connecticut, Florida, Georgia, Illinois, Maine, Maryland, Michigan, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oregon, Texas, Virginia, and Washington. The Commonwealth Fund. "State Balance-Billing Protections." (February 2021). https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.

¹²⁸ The states that have passed limited legislation include Arizona, Delaware, Indiana, Iowa, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, Nevada, North Carolina, Pennsylvania, Rhode Island, Vermont, and West Virginia. The Commonwealth Fund. "State Balance-Billing Protections." (February 2021). https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.

¹²⁹ The Commonwealth Fund. "State Balance-Billing Protections." (November 2020). https://www.commonwealthfund.org/sites/default/files/2020-12/Hoadley_state_balance_billing_protections_11302020.pdf.

¹³⁰ Public Law 116–260 (December 27, 2020).

health insurance coverage in Subchapter B of chapter 100 of the Code, Part 7 of ERISA, and Part D of title XXVII of the PHS Act. Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A–1, which contain limitations on cost sharing and requirements regarding the timing of initial payments for emergency services furnished by nonparticipating providers and emergency facilities, and for nonemergency services furnished by nonparticipating providers at certain participating health care facilities. Section 102 of the No Surprises Act also added 5 U.S.C. 8902(p) requiring FEHB carriers, facilities, and providers to comply with requirements described in applicable provisions with respect to FEHB covered individuals. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A–1 to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A–2, which contain limitations on cost sharing and requirements for the timing of initial payments for nonparticipating providers of air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process described in Code section 9816, ERISA section 716, and PHS Act section 2799A–1. The No Surprises Act provisions that apply to health care providers and facilities, and providers of air ambulance services, such as 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.

On July 13, 2021, the Departments and OPM published the July 2021 interim final rules.¹³¹ The July 2021 interim final rules implemented provisions of the No Surprises Act to 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.

These interim final rules build upon the protections in the July 2021 interim

¹³¹ 86 FR 36872 (July 13, 2021).

final rules and implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), PHS Act sections 2799A–1(c) and 2799A–2(b), and 5 U.S.C. 8902(p). The Federal IDR process will permit group health plans, health insurance issuers offering group or individual health insurance coverage, FEHB carriers, and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances.

Furthermore, these interim final rules extend the balance billing protections related to external reviews to grandfathered plans, including non-Federal governmental plans and individual market plans. The definitions of group health plan and health insurance issuer that are cited in section 110 of the No Surprises Act include both grandfathered and non-grandfathered plans and coverage. Accordingly, the practical effect of section 110 of the No Surprises Act is that grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Grandfathered and non-grandfathered plans must comply either with a state external review process or the Federal external review process. The disclosure requirements of the Federal external review process require: (1) A preliminary review by plans of requests for external reviews; (2) Independent Review Organizations (IROs) to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans to notify the claimant and IRO if it reverses its decision; (6) the IRO to notify the claimant and plan of the result of the final external review; and (7) the IRO to maintain records for 6 years.

Additionally, these interim final rules implement provisions of the No Surprises Act that require health care providers and health care facilities to furnish good faith estimates upon request or upon the scheduling of items or services for uninsured (or self-pay) individuals. In order to implement these good faith estimate provisions under

PHS Act section 2799B–6(1) and 2799B–6(2)(B), as added by section 112 of the No Surprises Act, HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and establish requirements for providing a good faith estimate to uninsured (or self-pay) individuals.

PHS Act section 2799B–6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such items or services (including any items or services that are reasonably expected to be provided in conjunction with such scheduled items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes (*i.e.*, ICD, CPT, HCPCS, DRG and/or NDC codes) for any such items or services. These interim final rules include definitions of certain terms, requirements for the providers and facilities, content requirements, and methods and manner requirements for issuing good faith estimates consistent with the provisions of PHS Act sections 2799B–6, 2799B–6(1), and 2799B–6(2)(B).

PHS Act section 2799B–7, as added by section 112 of the No Surprises Act, provides further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received a good faith estimate of expected charges from a provider or facility, and who, after being furnished the item or service, is billed for charges that are substantially in excess of the estimate, may seek a determination from a SDR entity of the amount to be paid. HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process including specific definitions related to the patient-provider dispute resolution process. HHS is also codifying provisions related to the eligibility of an item or service for the patient-provider dispute resolution process, certification and selection of SDR entities, fees associated with the patient-provider dispute resolution process, and deferral to state patient-provider dispute resolution processes.

Consistent with Executive Orders 13985 and 13988, and all civil rights laws and protections cited previously, these interim final rules include provisions designed to address and

increase the HHS' understanding of barriers underserved and minority communities face in accessing the protections established in the No Surprises Act, including the provision of good faith estimates for uninsured (or self-pay) individuals, and the process for patient-provider dispute resolution.

The Departments seek comment from individuals from racial/ethnic minority and underserved communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and individuals with health literacy needs, and providers who serve these individuals, to help identify emerging, persistent, or perceived barriers to individuals accessing and understanding these processes, rights, and protections, and other provisions of the No Surprises Act included in this rule, and policies to address and remove these barriers.

1.2. Summary of Impacts

Plans, issuers, FEHB carriers, health care providers, facilities, and providers of air ambulance services will incur costs to comply with the requirements in these interim final rules, as discussed later in this section of this preamble. However, the Departments and OPM have determined that the benefits of these interim final rules justify the costs.

The provisions in these interim final rules will help ensure that participants, beneficiaries, and enrollees with health coverage are protected from surprise medical bills. When plans, issuers, and FEHB carriers participate in the Federal IDR process, 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. One study found that surprise billing decreased by 34 percent in New York State between 2015 and 2018, when the state implemented an IDR process.¹³² The study also found that New York's Out-of-Network Law¹³³ saved consumers over \$400 million from the date of implementation with respect to emergency services alone.¹³⁴

¹³² Marion Mass. "Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart." *Morning Consult*. (March 2020). <https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/>.

¹³³ NY Fin Serv L § 605 (2014).

¹³⁴ New York State Department of Financial Services. "New York's Surprise Out-Of-Network

The information regarding the good faith estimates furnished by providers and facilities will allow uninsured (or self-pay) individuals to have access to information about health care pricing before receiving care. This information will allow uninsured (or self-pay) individuals to evaluate options for receiving health care, make cost-conscious health care purchasing decisions, and reduce surprises in relation to their health care costs for those items and services. Additionally, uninsured (or self-pay) individuals may use the good faith estimate for comparison with actual billed charges received after items or services are furnished. If the billed charges are substantially in excess of the good faith estimate, an uninsured (or self-pay) individual may seek a determination from an SDR entity under the patient-provider dispute resolution process.

HHS will request information from uninsured (or self-pay) individuals in order to initiate the patient-provider dispute resolution process. This information will be used to help determine eligibility for the patient-provider dispute resolution process and is necessary for determining which provider or facility should be contacted for dispute resolution. Providers and facilities are required to submit information to an SDR entity to inform the SDR entity's payment determination decisions.

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.

TABLE 1: Accounting Statement

Benefits:
Non-quantified benefits of the Federal IDR process for the population with health coverage:

- Increased protection for participants, beneficiaries, and enrollees from surprise bills from out-of-network providers by creating a process for plans, issuers, FEHB carriers, and nonparticipating providers and facilities to resolve disputes regarding certain out-of-network rates. Note that, unless specified otherwise, providers include providers of air ambulance services.

- Increased awareness of expected charges for items or services, reduction in financial anxiety and out-of-pocket expenses for individuals with health coverage because individuals will be able to meet their deductibles and out-of-pocket maximum limits sooner.

- Increased access to care for individuals with health coverage that may have otherwise forgone or delayed needed treatment due to concerns over the potential for high out-of-pocket expenses.

Non-quantified benefits of the patient-provider dispute resolution process for uninsured (or self-pay) individuals:

- Increased awareness of expected charges for items or services, reduction

in financial anxiety, more informed health care decisions, and protection for uninsured (or self-pay) individuals by requiring providers and facilities to furnish good faith estimates for scheduled or requested items and services.

- Improved access to care for uninsured (or self-pay) individuals that may have otherwise forgone or delayed needed treatment due to concerns over receiving unexpected large bills.

- Protection for uninsured (or self-pay) individuals from excessive surprise bills from providers or facilities by establishing a patient-provider dispute resolution process that may result in lower payments if the SDR entity determines the amount to be paid by the uninsured (or self-pay) individual to the provider or facility are lower than the billed charges.

Non-quantified benefits regarding external review:

- Increased access to benefits for some individuals.

- Reduced incidence of excessive delays and inappropriate denials, averting serious, avoidable lapses in access to quality health care and resultant injuries and losses to participants, beneficiaries, enrollees, and FEHB covered individuals.

- Potential increase in confidence and satisfaction among participants, beneficiaries, and enrollees in their health care benefits.

- Improved awareness among plans, issuers, and FEHB carriers of participant, beneficiary, enrollee, FEHB covered individuals, and provider concerns.

COSTS TO PLANS, ISSUERS, AND FEHB CARRIERS

Costs (in millions)	Estimate	Year dollar	Discount rate	Period covered
Annualized	\$517.12	2021	7 percent	2022–2031
Monetized (\$/Year)	491.44	2021	3 percent	2022–2031

The annualized cost estimates reflect estimated costs associated with the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities, the Federal IDR process for providers of air ambulance services, IDR entity certification and reporting requirements, the Federal IDR process for the uninsured, SDR entity certification, and the extension of the external review to grandfathered plans and claims under certain provisions of the No Surprises Act. The Departments

estimate a total cost of \$760.95 million in the first year and \$440.67 million going forward.

Costs to the Government:
The Federal Government will incur costs to build and maintain the Federal IDR portal and to implement and administer the patient-provider dispute resolution process. The maintenance costs for the Federal IDR portal are split between the Federal IDR process and the patient-provider dispute resolution process, based on anticipated volume for each program. The costs associated

with the Federal IDR portal are estimated to be a one-time cost of \$6 million in fiscal year 2021 and annual costs of \$1 million going forward. The costs associated with the patient provider dispute resolution process are estimated to be a one-time cost of \$10 million in fiscal year 2021 and an annual cost of \$12 million going forward. Additionally, the costs associated with the Federal external review costs are estimated to be \$1.16

Protection Law Report on the Independent Dispute Resolution Process.” (September 2019).

million in fiscal year 2021 and \$567,000 annually going forward.

Transfers:

Non-quantified transfers associated with the Federal IDR process for the population with health coverage:

- Potential transfers from providers who had previously balance billed for out-of-network claims to individuals who are no longer responsible for paying these balance bills.

- Potential transfers from plans, issuers, and FEHB carriers who were previously not responsible for out-of-network balance bills to providers and facilities that will submit out-of-network balance bills to plans, issuers, and FEHB carriers as a result of the interim final rules.

- Potential transfers from plans, issuers, and FEHB carriers to participants, enrollees, and beneficiaries if the Federal IDR process results in lower premiums.

- Potential transfers from participants, enrollees, and beneficiaries to plans, issuers, and FEHB carriers if the Federal IDR process results in higher premiums.

- Potential transfers to the Federal Government in the form of reduced Premium Tax Credits if the Federal IDR process results in the lower premiums.

- Potential transfers from the Federal Government to eligible enrollees, in the form of increased Premium Tax Credits payments if the Federal IDR process results in an increase in premiums.

- Potential transfers from individuals with health coverage who pay premiums to individuals with large out-of-network bills and uninsured individuals if the Federal IDR process results in an increase in premiums.

- Potential transfers from providers, facilities, and providers of air ambulance services to plans, issuers, and FEHB carriers if some providers, facilities, and providers of air ambulance services collect lower out-of-network payments.

- Potential transfers between providers, facilities, and providers of air ambulance services and individuals with health coverage, depending on the weight place on the QPA in payment determinations under the Federal IDR process. The presumption in favor of the QPA in the Federal IDR process may result in transfers from providers and facilities to participants, beneficiaries, and enrollees.

Non-quantified transfers associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals:

- Potential transfer of the patient-provider dispute resolution administrative fee from the provider or

facility to the uninsured (or self-pay) individuals if the SDR entity makes a payment determination in favor of the uninsured (or self-pay) individual.

- Potential transfer from uninsured (or self-pay) individuals to providers or facilities if the SDR entity makes a payment determination that is higher than the good faith estimate.

Non-quantified transfers associated with external review:

- Potential transfer from plans, issuers, and FEHB carriers to participants, beneficiaries, and enrollees now receiving payment for denied benefits.

1.3. Affected Entities

These interim final rules will affect health care patients, health care providers, health care facilities, providers of air ambulance services, self-insured plans, issuers, and FEHB carriers.

In 2019, there were 1,553 issuers in the U.S. health insurance market, of which 1,298 issuers serve the individual market, 586 issuers serve the small group market, and 788 issuers serve the large group market.¹³⁵ Additionally, the Departments and OPM estimate that 46 issuers are FEHB carriers. While there is a significant amount of research that demonstrates the prevalence of surprise billing, as discussed in the July 2021 interim final rules, the Departments do not have data on what percentage of health insurance issuers cover individuals who experience surprise billing. However, given the size and scope of insurance companies, the Departments assume that all health insurance issuers will be affected by these interim final rules. The Departments estimate that 8.5 percent, or approximately 132 issuers are considered small under the Small Business Administration's (SBA) size standards.¹³⁶

¹³⁵ Centers for Medicare and Medicaid Services. "Medical Loss Ratio Data and System Resources" (2019). <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

¹³⁶ The issuers affected by these interim final rules are expected to fall under the industry of Direct Health and Medical Insurer Carriers, NAICS 524114. According to the SBA Table of Size Standards, an issuer is considered small if its annual receipts are less than \$41.5 million. (See Small Business Administration. "Table of Size Standards." (August 2019). <https://www.sba.gov/document/support-table-size-standards>.) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across establishments, the Departments estimate that 132, or 8.5 percent of issuers are small. (See Census Bureau. "2017 SUBS Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size." (May 2021). <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.)

Of the plans that filed a Form 5500 in 2018, 25,500 plans were self-insured.¹³⁷ The Departments do not have data on what percentage of self-insured group health plans cover individuals who have received a surprise bill. The Departments request comment on how many group health plans will be affected by these interim final rules.

In 2018, 296.2 million individuals had health insurance. Of the 213.2 million individuals with private insurance, 178.4 million had employer-sponsored insurance and 34.8 million had other private insurance, including individual market coverage.¹³⁸ One study looked at claims data from a large commercial issuer for the period 2010–2016 and found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill.¹³⁹ The Departments estimate that these interim final rules will directly affect individuals with private health coverage who visit an emergency room, visit a hospital, or are transported by an air ambulance.

The Departments expect that the Federal IDR process will have overflow effects of decreasing the incidence of surprise medical bills in general, even for patients who do not have a claim that goes to the Federal IDR process. The Federal IDR process relies on a "baseball-style" arbitration, in which each party submits their desired amount, and the certified IDR entity selects one of the two offers submitted. This differs from other types of arbitration, in which the arbitrator would often select a value between the two submissions. Accordingly, this process encourages each party to submit a reasonable offer. Further, the parties involved will need to weigh the costs associated with the Federal IDR process, including payment of the administrative fee and the certified IDR entity fee if their offer is not chosen. The Departments are of the view this may serve as an incentive to not only submit reasonable offers once the Federal IDR

¹³⁷ Stewart, Al. "Report to Congress: Annual Report on Self-Insured Group Health Plans." (March 2021). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2021.pdf>.

¹³⁸ Employee Benefits Security Administration. "Health Insurance Coverage Bulletin." (March 2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

¹³⁹ 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.

process has been initiated, but also to conduct business in a way to avoid ending up in the Federal IDR process altogether. The Departments cannot estimate how large these overflow effects will be on a national basis; however, the experience in New York State provides a point of reference. In 2018, in New York State, surprise billing decreased by 34 percent after the IDR process was implemented.¹⁴⁰

Surprise billing occurs more often in specialties that are not shopped.¹⁴¹ A recent survey looked at 13.8 million visits to 35,000 unique providers in six specialties in 2017 to estimate the

percent of providers with at least one out-of-network claim by specialty and whether the procedure was inpatient or outpatient. The survey found that less than half of specialist providers surveyed billed at least once on an out-of-network basis. Their findings are shown in the last four columns in Table 2.¹⁴² The second column provides the number of active physicians in each specialty from the American Association of Medical Colleges.¹⁴³ As set forth in Table 2, the prevalence of providers who bill on an out-of-network basis and the average frequency of visits that are billed out-of-network among

providers who do bill on an out-of-network basis varies by specialty.

The Departments estimate that 16,992 emergency and other health care facilities will be affected by these interim final rules, including 6,090 hospitals,¹⁴⁴ 29,227 diagnostic and medical laboratories,¹⁴⁵ 270 independent freestanding emergency departments,¹⁴⁶ 9,280 ambulatory surgical centers,¹⁴⁷ and 1,352 critical access hospitals. The Departments acknowledge that this estimate double counts some entities, particularly with regard to facilities that have laboratories in-house.

TABLE 2—PHYSICIANS WITH OUT-OF-NETWORK CLAIMS

	Number of active physicians ¹⁴⁸	Percent of providers with at least one out-of-network claim, 2017 ¹⁴⁹ (%)		Mean percent of visits with services billed out-of-network for providers who billed out-of-network at least once ¹⁵⁰ (%)	
		Inpatient	Outpatient	Inpatient	Outpatient
Emergency	45,134	44.1	49.3	14.7	34.3
Pathology	12,640	44.0	33.0	44.3	31.4
Radiology	28,017	27.7	32.5	11.0	17.9
Anesthesiology	42,249	57.0	31.8	11.3	28.4
Behavioral Health/Psychiatry	38,778	29.8	14.9	21.4	24.4
Cardiovascular	22,514	17.9	17.0	6.8	8.3

As seen in Table 2, among the specialist providers considered, emergency physicians were most likely to bill on an out-of-network basis at least once; however, emergency physicians account for less than 5 percent of total physicians.¹⁵¹ The

Departments estimate that 15 percent, or 140,270, of physicians,¹⁵² on average, bill on an out-of-network basis and will be affected by these interim final rules. The Departments estimate that 44.1 percent, or approximately 61,890 physicians, practice in a small business

under the SBA size standards.¹⁵³ The Departments seek comment on these estimates.

Physician staffing companies, which allow for medical facilities to hire the services of a medical professional without hiring the medical professional

¹⁴⁰ Marion Mass. “Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.” *Morning Consult*. (March 2020). <https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/>.

¹⁴¹ Greaney, Thomas. “Surprise Billing: A Window into the U.S. Health Care System.” American Bar Association. (September 2020). https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/.

¹⁴² Fugelsten Biniek, Jean, et al. “How Often Do Providers Bill Out of Network?” Health Care Cost Institute. (May 2020). <https://healthcostinstitute.org/out-of-network-billing/how-often-do-providers-bill-out-of-network>.

¹⁴³ 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>.

¹⁴⁴ American Hospital Association. “Fast Facts on U.S. Hospitals, 2021.” (January 2021). <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁴⁵ IBIS World. Definitive Healthcare. “Diagnostic & Medical Laboratories Industry in the US—Market Research Report?” (May 2021). <https://www.ibisworld.com/industry-statistics/number-of-businesses/diagnostic-medical-laboratories-united-states/>.

¹⁴⁶ Emergency Medicine Network. “2018 National Emergency Department Inventory.” (2021). <https://www.emnet-usa.org/research/studies/medi/medi2018/>.

¹⁴⁷ Definitive Healthcare. “How Many Ambulatory Surgery Centers are in the US?” (April 2019). <https://www.definitivehc.com/blog/how-many-ascs-are-in-the-us>.

¹⁴⁸ See 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>.

¹⁴⁹ See Fugelsten Biniek, Jean, et al. “How Often Do Providers Bill Out of Network?” Health Care Cost Institute. (May 2020). <https://healthcostinstitute.org/out-of-network-billing/how-often-do-providers-bill-out-of-network>.

¹⁵⁰ *Id.*
¹⁵¹ 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 percent).

¹⁵² The Departments do not have data on the percentage of physicians who bill out of network across all specialties; however, it is likely lower than the percentage of physicians who bill out of network across the six specialties cited in the cited study. The six specialties cited account for

approximately 20 percent of physicians. Based on the information presented in Table 2, the Departments estimate that on average, just over 30 percent of physicians in these specialties had at least one out-of-network claim. The Departments assumes that the other 80 percent of physicians bill on an out-of-network basis just 10 percent of the time. The Departments approximate the percent of physicians who bill on an out-of-network basis to be: (20 percent × 32 percent) + (10 percent × 80 percent) = 14.4 percent. As an approximation, the Departments round this to 15 percent.

¹⁵³ The physicians affected by these interim final rules are expected to fall under the industry of Offices of Physicians, NAICS 62111. According to the SBA Table of Size Standards, an office of physicians is considered small if its annual receipts are less than \$12.0 million. (See Small Business Administration. “Table of Size Standards.” (August 2019). <https://www.sba.gov/document/support-table-size-standards>.) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across employees, the Departments estimate that 61,890, or 44.1 percent of physicians work in an office considered a small business. (See Census Bureau. “2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.” (May 2021). <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.)

themselves, may also be affected by these interim final rules, as they provide services in medical specialties that are not shopped, including emergency, radiology, and anesthesiology.¹⁵⁴ Physician staffing companies often bill patients directly for services rendered.¹⁵⁵ Within recent years, the growth of the health care staffing industry has accelerated, driven by staffing shortages in health care facilities as the population ages.¹⁵⁶ A survey of 200 health care executives found that 85 percent of surveyed health care facility managers used temporary physicians within the last year, and 72 percent were seeking more temporary physicians.¹⁵⁷ There are approximately 40 health care staffing firms providing these services.¹⁵⁸

Furthermore, in 2014, it was estimated that there were 1,073 businesses in the air ambulance service industry.¹⁵⁹ One study estimated that between 2014 and 2017, 77 percent of air ambulance claims were out-of-network.¹⁶⁰ The Departments do not have data on the number of providers of air ambulance services that submit out-of-network claims; however, given the prevalence of out-of-network billing among providers of air ambulance services, the Departments assume that all businesses in the industry will be affected by these interim final rules. The Departments estimate that 59.2 percent, or approximately 635 providers of air

¹⁵⁴ Appelbaum, Eileen and Rosemary Batt. "Private Equity and Surprise Medical Billing." (2021). Institute for New Economic Thinking. <https://www.ineteconomics.org/perspectives/blog/private-equity-and-surprise-medical-billing>.

¹⁵⁵ Moody's Investor Service. "Surprise Billing Ban to Constrain Physician Firms' Cash Flow, Curb Negotiating Clout for Air Ambulances." (2021). https://www.moody.com/research/Moody-s-Surprise-billing-ban-to-constrain-physician-staffing-firms-cash-PBC_1263184.

¹⁵⁶ Schwartz, Chris. "Overview of the Temporary Healthcare Staffing Sector." Blue Pencil Strategies. <https://healthywork.uic.edu/wp-content/uploads/sites/452/2019/08/Temporary-Healthcare-Staffing-Fact-Sheet.pdf>.

¹⁵⁷ Gooch, Kelly. "Temporary Physicians Staffing: Why and How Often It Occurs." Becker's Hospital Review. (2020). <https://www.beckershospitalreview.com/workforce/temporary-physician-staffing-why-and-how-often-it-occurs.html>.

¹⁵⁸ Schwartz, Chris. "Overview of the Temporary Healthcare Staffing Sector." Blue Pencil Strategies. <https://healthywork.uic.edu/wp-content/uploads/sites/452/2019/08/Temporary-Healthcare-Staffing-Fact-Sheet.pdf>.

¹⁵⁹ IBIS World. "Air Ambulance Service Industry in the US—Market Research Report." (December 2020). <https://www.ibisworld.com/united-states/market-research-reports/air-ambulance-services-industry/>.

¹⁶⁰ Brown, Erin, et al. "The Unfinished Business of Air Ambulance Bills." Health Affairs Blog, March 26, 2021. <https://www.healthaffairs.org/doi/10.1377/hblog2010323.911379/full/>.

ambulance services, are considered small under the SBA size standards.¹⁶¹

IDR entities must be certified under the standards and procedures set forth in guidance by the Departments. In order to be certified, an entity must have sufficient expertise in arbitration and claims administration, managed care, billing and coding, medical, and legal matters, with sufficient staffing to make determinations within 30 business days allowed for such payment determinations. Additionally, IDR entities must meet appropriate indicators of fiscal integrity and stability and maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the AAA, the AHLA, or a similar organization), among other requirements.

The National Association of Independent Review Organizations is an association of URAC-accredited independent review organizations, and in 2021, they had 29 members.¹⁶² While this does not represent the entire pool of independent review organizations, this offers insight into the number of potential entities that may seek certification as IDR entities. In 2019, New York had certified three IDR entities to handle the state's IDR process.¹⁶³ In 2018, the state of New York accounted for 5.8 percent of the private insurance market.¹⁶⁴ The

¹⁶¹ The providers of air ambulance services affected by these interim final rules are expected to fall under the industry of Ambulance Services, NAICS 621910. According to the SBA Table of Size Standards, an air ambulance service provider is considered small if its annual receipts are less than \$16.5 million. (See Small Business Administration. "Table of Size Standards." (August 2019). <https://www.sba.gov/document/support-table-size-standards>.) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across establishments, the Departments estimate that 635, or 59.2 percent of providers of air ambulance services are small. See Census Bureau. "2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size." (May 2021). <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

¹⁶² Laceywell, Linda. "New York's Surprise Out-of-Network Protection Law." Patient Choice Coalition." (September 2019). <http://www.patientchoicecoalition.com/blog/2019/11/22/report-on-the-independent-dispute-resolution-process/>.

¹⁶³ Id.

¹⁶⁴ In 2018, 10.5 million individuals had employer-sponsored insurance and 1.8 million individuals had other private insurance in New York State, while 178.4 million individuals had employer-sponsored insurance and 34.8 million individuals had other private insurance nationally.

Departments recognize that the health care and surprise billing experiences across states are heterogeneous; however, if this proportion were uniform across the country, there would be approximately 52 IDR entities. Based on these two benchmarks, the Departments estimate that there will be 50 IDR entities that will seek certification by the Departments. Within these 50 entities, HHS estimates that there will be between one and three contracted SDR entities, depending on the anticipated volume of patient-provider dispute resolution cases and other factors necessary for administering an efficient program.

Health care providers and health care facilities are required to furnish a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request. In 2019, there were approximately 938,966 active physicians,¹⁶⁵ 6,090 hospitals,¹⁶⁶ 9,280 ambulatory surgical centers,¹⁶⁷ and 1,352 critical access hospitals.¹⁶⁸ As of 2019, there were approximately 29,349,300 uninsured individuals in the United States.¹⁶⁹ HHS estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement¹⁷⁰ based on the

The Departments estimates New York accounts for 5.8 percent of the private insurance market $((10.5 + 1.8)/(178.4 + 34.8) = 5.8 \text{ percent})$. See Employee Benefits Security Administration. "Health Insurance Coverage Bulletin." (March 2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

¹⁶⁵ <https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-us-doctor-medicine-us-md-degree-specialty-2019>.

¹⁶⁶ <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁶⁷ <https://blog.definitivehc.com/how-many-ascs-are-in-the-us#:~:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers>.

¹⁶⁸ <https://www.flexmonitoring.org/historical-cah-data-0>.

¹⁶⁹ This figure includes those without health insurance and those who have coverage under the Indian Health Service only. Source: <https://www.kff.org/other/state-indicator/total-population/?dataView=1¤tTimeframe=0&selectedDistributions=uninsured&selectedRows=%2B%22wrapups%22:%2B%22united-states%22:%2B%2D%2D%2D%2D&sortModel=%2B%22colId%22:%22Location%22,%22sort%22:%22asc%22%2D>.

¹⁷⁰ The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually \times 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. See Squitieri, Lee et al. "Resuming Elective Surgery during Covid-19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?." *Plastic and reconstructive*

number of nonemergency elective procedures (surgical and non-surgical) performed annually multiplied by the percentage of uninsured (or self-pay) individuals (9.2%), and HHS assumes that some uninsured individuals will forego elective procedures because of cost. HHS also assumes that a certain number of good faith estimates will be furnished only upon request, increasing the number of good faith estimates from that of the total for scheduled items and services.

These interim final rules also implement a patient-provider dispute resolution process that applies to uninsured (or self-pay) individuals whose billed charges exceed the expected charges in the good faith estimate for a provider or facility by \$400 or greater. HHS does not have data on the percentage of how many uninsured (or self-pay) individuals will initiate the patient-provider dispute resolution process. For the purposes of the estimates in this section, HHS relied on the experience of New York State. From 2015 to 2018, New York State had a total of 1,486 disputes involving surprise bills submitted to the state IDR process, and 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to being self-insured.¹⁷¹ For the purposes of this analysis, HHS assumes that, going forward, New York State will continue to see 40 IDR adjudications each year involving surprise medical bills for self-insured individuals. Accordingly, HHS estimates that there will be 26,659 claims that result in patient-provider dispute resolution cases each year.¹⁷² These interim final rules establish requirements that an SDR entity must

meet the same certification standards as a certified IDR entity. HHS estimates that there will be between one and three contracted SDR entities depending on the anticipated volume of patient-provider dispute resolution cases and other factors necessary for administering an efficient program. HHS will assess if a potential SDR entity meets the certification standards as part of the contracting process.

Furthermore, the interim final rules extend the balance billing protections related to external review to grandfathered plans. Prior to the interim final rules, the Departments estimate that there are approximately 8.1 million participants in ERISA-covered plans in states that have no external review laws or whose laws do not meet the Federal minimum requirements.¹⁷³ These estimates lead to a total of 92.5 million participants not having access to external review. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants¹⁷⁴ and that there will be approximately 12,304 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review.¹⁷⁵ Therefore, the Departments expect that there will be about 15,942 requests for external review.¹⁷⁶

1.4. Benefits

Federal IDR Process

In the past, information asymmetries regarding health care costs and provider or facility network status between individuals and plans, issuers, and providers have left individuals vulnerable to surprise billing. These interim final rules will provide a structure to guide the resolution of pricing disparities in a way that will prevent a patient's information asymmetry from resulting in a surprise bill, thus alleviating the market failure.

As a result of these interim final rules, individuals with health coverage will only be liable for their in-network cost-sharing amounts when receiving care from nonparticipating providers at participating facilities (in certain circumstances), nonparticipating emergency facilities, and nonparticipating providers of air ambulance services. Accordingly, these individuals are likely to see lower out-of-pocket costs, reduced anxiety, reduced financial stress, and lower medical debt. Further, these payments will now count towards their deductible and maximum out-of-pocket limits, allowing individuals to reach those limits sooner. A significant number of individuals forgo or delay care due to the cost of care.¹⁷⁷ 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.

Further, these interim final rules create a system in which disputes may be resolved in a consistent and efficient manner. These interim final rules are intended to minimize reliance on the Federal IDR process and encourage parties to submit reasonable offers and allow for more efficient price discovery. By requiring the non-prevailing party to pay the certified IDR entity fees, these interim final rules increase the financial stakes for parties that submit an offer that is unreasonably high or low. However, if the parties agree upon a settlement, after initiation, but prior to determination by the certified IDR entity, each party must pay half of the certified IDR entity's fees, unless the parties agree otherwise on a method for allocating the fees. Thus, parties have an incentive to choose a settlement compared to the Federal IDR process. During negotiations, providers may be more willing to accept a lower price and similarly, plans, issuers, and FEHB carriers may be more willing to offer a higher price.

Similarly, these interim final rules are intended to encourage the settlement of multiple claims. Under these interim final rules, the party that initiates the Federal IDR process is suspended from taking the same party to arbitration for an item or service that is the same or similar item or service as the qualified

surgery. Global open vol. 9,2 e3442. 18 Feb. 2021. doi:10.1097/GOX.00000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

¹⁷¹ https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf.

¹⁷² The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually \times 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is \$400 or more than the total expected charges in the good faith estimate for the provider or facility, therefore $3,332,326 \times 10\% = 333,232$. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore $333,232 \times 8\% = 26,659$.

¹⁷³ These states are Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.

¹⁷⁴ AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008.

¹⁷⁵ North Carolina Department of Insurance. "Health Insurance Smart NC: Annual Report on External Review Activity 2013." <https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531>.

¹⁷⁶ $12,304/0.75 = 15,942$.

¹⁷⁷ According to a Kaiser Family Foundation analysis of National Health Interview Survey data, in 2019, 10.5 percent of adults reported forgoing or delaying medical care due to costs. Reference: Krutika, Amin, Gary Claxton, Giorlando Ramirez, and Cynthia Cox (2021). "How Does Cost Affect Access to Care?" Peterson-KFF Health System Tracker. Available at <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/>.

IDR item or service already subject to a certified IDR entity's determination for 90 calendar days following a payment determination. Furthermore, these interim final rules permit multiple qualified IDR items and services to be batched together in a single payment determination proceeding to encourage efficiency; however, the batched items and services must involve the same provider or group of providers, the same facility, the same provider of air ambulance services, the same plan or issuer, treatments involving the same or similar items or services (as determined by service codes), and have to occur within a single 30-business-day period (or during the 90-calendar-day suspension period). By batching similar qualified IDR items and services, these interim final rules may reduce the per-service cost of the Federal IDR process and potentially the aggregate administrative costs, since the Federal IDR process is likely to exhibit at least some economies of scale.¹⁷⁸ For example, the per-service cost of a payment determination involving ten services is likely to be lower than the per-service cost of a payment determination involving five services. Thus, these interim final rules may result in cost savings for plans, issuers, and providers. The Departments do not have data or a way to estimate how prevalent batching will be, and thus the potential cost savings that may result, in comparison to a hypothetical IDR process without batching. The Departments seek comment and data on this topic, if available.

In addition, these interim final rules prohibit conflicts of interest in the selection of certified IDR entities. The selected certified IDR entity cannot be a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility or a provider of air ambulance services. Additionally, the selected certified IDR entity cannot be an affiliate of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility or a provider of air ambulance services. The selected certified IDR entity cannot be an affiliate or subsidiary of a

professional or trade association representing group health plans; health insurance issuers; FEHB carriers; or providers, facilities, or providers of air ambulance services. Also, the selected certified IDR entity and its personnel cannot have a material familial, financial, or professional relationship with a party to the payment determination being disputed. By prohibiting conflicts of interest, these interim final rules will help ensure that the selected certified IDR entity will take both parties into full consideration during arbitration and ensure that the resolution of the dispute is conducted fairly.

Furthermore, these interim final rules dictate what factors the certified IDR entities may consider for their decisions. Specifically, these interim final rules require that certified IDR entities consider the QPA and requires them to consider other relevant factors, to the extent credible information is provided by the parties, while not allowing for the consideration of usual and customary rates, billed charges of the provider, or public payor rates, such as those of Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, chapter 17 of title 38, United States Code, or demonstration projects under title XI of the Social Security Act.

The Departments seek comment addressing the benefits that will be associated with these interim final rules. The Departments also seek comment on how the interim final rules will affect individuals from minority and underserved communities and providers who serve these individuals.

Protections for the Uninsured

Health insurance and health care costs are critical determinants of access to health care and are central reasons for existing health inequities.¹⁷⁹ In the past decade, while overall rates of health insurance coverage have increased, the rates of health insurance coverage among most minority groups continue to be disproportionately lower than among non-minority groups. Estimates from the Centers for Disease Control and Prevention (CDC) National Health Interview Survey (NHIS), suggest that approximately 30 million U.S. residents lacked health insurance in the first half of 2020.¹⁸⁰ Prior to the COVID-19

pandemic, according to information collected in the Current Population Survey Annual Social and Economic Supplement (CPS ASEC) and the American Community Survey (ACS), in 2019, 8.0% of people, or 26.1 million individuals, did not have health insurance at any point during the year.¹⁸¹ Additionally, the most recent ACS data documents the largest annual increase in the number of uninsured children from 2018 to 2019 since the survey began asking about health insurance in 2008. The child uninsured rate increased from 5.2% in 2018 to 5.7% in 2019.¹⁸²

The provisions in these interim final rules will protect uninsured (or self-pay) individuals by allowing them to obtain a good faith estimate of expected charges from providers and facilities prior to receiving scheduled items and services and upon request. With this information, uninsured (or self-pay) individuals may be more likely to consider and compare costs across providers or facilities prior to or upon scheduling an item or service to help inform decisions regarding costs for an item or service. Additionally, these interim final rules protect these uninsured (or self-pay) individuals from receiving excessive surprise bills from providers and facilities, and allow an uninsured (or self-pay) individual to seek a determination through the patient-provider dispute resolution process if billed charges for items or services from a provider or facility are substantially in excess of the expected charges listed on the good faith estimate.

The patient-provider dispute resolution process further protects uninsured (or self-pay) individuals as the process may result in lower payments. During the dispute resolution process, the SDR entity must review any documentation submitted by the uninsured (or self-pay) individual or their authorized representative, or a provider or facility, and must make a determination as to whether the health care provider or health care facility has provided credible information for each billed item or service, including an item or service that did not originally appear on the good faith estimate, to demonstrate that the difference between the billed charge and the expected

¹⁷⁸ Fielder, Matthew, Loren Adler, and Benedic, Ippolito. "Recommendations for Implementing the No Surprises Act." U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/>.

¹⁷⁹ "Mirror, Mirror 2021: Reflecting Poorly." The Commonwealth Fund (2021). <https://www.commonwealthfund.org/publications/fund-reports/2021/aug/mirror-mirror-2021-reflecting-poorly>.

¹⁸⁰ "Trends in the US Uninsured Population 2010-2020." APSE Office of Health Policy (2020). <https://aspe.hhs.gov/system/files/pdf/265041/trends-in-the-us-uninsured.pdf>.

¹⁸¹ Keisler-Starkey, Katherine and Lisa N. Bunch. "Health Insurance Coverage in the United States: 2019." (2020) <https://www.census.gov/library/publications/2020/demo/p60-271.html>.

¹⁸² "Census Data Show Largest Annual Increase in Number of Uninsured Children in More Than a Decade." <https://ccf.georgetown.edu/2020/09/15/census-data-show-decades-largest-annual-increase-in-number-of-uninsured-children/>.

charge in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS is of the view that this helps ensure that the SDR entity review is comprehensive and that the facts and circumstances for the billed charge for each item or service are considered by the SDR entity. HHS is also of the view that this approach ensures that the uninsured (or self-pay) individual is only billed charges that reflect medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. This dispute resolution process protects the uninsured (or self-pay) individual from unexpected charges in cases where there are extra charges based on items or services that are not medically necessary, or could have been reasonably foreseen and thus included on the good faith estimate.

These provisions also provide protections when an uninsured (or self-pay) individual receives a bill that includes providers or facilities that were not included in the good faith estimate, specifically if a co-provider or co-facility is replaced at the last moment by a different co-provider or co-facility. These interim final rules provide important consumer protections that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills by not allowing a provider or facility to essentially circumvent these protections simply due to not being directly represented on the good faith estimate. Therefore, HHS is of the view that it is necessary and appropriate for billed items or services of providers or facilities to be eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with an updated good faith estimate in accordance with 45 CFR 149.610(b)(2) then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charges for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

HHS recognizes that these particular situations may be more complex for an uninsured (or self-pay) individual to determine eligibility for dispute resolution since the provider or facility may not be reflected in the good faith estimate.

HHS is of the view that requiring an uninsured (or self-pay) individual to pay the entire cost of dispute resolution in cases where the provider or facility prevails in dispute resolution could be prohibitive for such an uninsured (or self-pay) individual to access the dispute resolution process. HHS is also concerned that requiring a provider or facility to pay dispute resolution costs when they do not prevail could impose a burden on the provider or facility and potentially provide an incentive for the provider or facility to raise prices on uninsured (or self-pay) individuals to account for potential dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether. Therefore, HHS is adopting an approach in which HHS will cover dispute resolution costs through contracts with SDR entities for the patient-provider dispute-resolution process. HHS estimates that the total costs to be paid for patient-provider dispute resolution to SDR entities to be \$10,633,600.¹⁸³ Such an approach ensures that the uninsured (or self-pay) individual would not be required to pay dispute resolution costs and as a result would not face a barrier to accessing the dispute resolution process. Additionally, as the provider or facility would not be required to pay dispute resolution costs, such approach would reduce the provider's or facility's incentives to increase prices or restrict an uninsured (or self-pay) individual's access to needed care.

In addition, PHS Act section 2799B-7 requires that the Secretary of HHS establish an administrative fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual to

¹⁸³ The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually \times 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forgo elective procedures because of costs. HHS assumes that 333,232 of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed amount that is \$400 or greater more than the total expected charges listed in the good faith estimate for the provider or facility, therefore $3,332,326 \times 10\% = 333,232$. The Department assumes that 8% of these individuals will engage the provider-patient dispute resolution process, therefore $333,232 \times 8\% = 26,659$. For the first year, HHS expects the SDR fee per arbitration to be about \$400 therefore $\$400 \times 26,659 = \$10,633,600$.

participate in such process. HHS intends to establish an administrative fee in guidance in a manner that will not create a barrier to an uninsured (or self-pay) individual's access to the patient-provider dispute resolution process. For the first year, HHS expects the fee to be no more than \$25.

Although HHS is of the view that requiring all parties to the dispute resolution to pay an administrative fee to offset some of the Federal costs for administering the patient-provider dispute resolution program is appropriate, only the non-prevailing party will be required to pay the administrative fee (either as a payment made directly to the SDR entity in the case of the uninsured (or self-pay) individual, or in a reduction in the final payment determination amount as in the case of the provider or facility). In cases where the SDR entity determines the payment amount the uninsured (or self-pay) individual pays is less than the billed charge, the SDR entity would apply a reduction equal to the administrative fee amount paid by the uninsured (or self-pay) individual to the payment amount to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services. HHS is of the view that requiring the SDR entity to apply a reduction equal to the administrative fee paid by the uninsured (or self-pay) individual to the payment amount is the appropriate approach as it simplifies the number of transactions. HHS anticipates collecting \$666,475¹⁸⁴ in administrative fees from an anticipated 26,659 cases, which will offset some of the costs of the patient-provider dispute resolution process, which is estimated to be \$12.6 million (which includes IDR portal system maintenance and contracting fees for SDRs) beginning in 2022, resulting in a total cost to the Federal Government of approximately \$12 million.

External Review Requirements

These interim final rules will help transform the external review process

¹⁸⁴ The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually \times 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. HHS assumes that 333,232 of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is at least \$400 more than the total expected charges listed in the good faith estimate for the provider or facility, therefore $3,332,326 \times 10\% = 333,232$. The Department assumes that 8% will engage the provider-patient dispute resolution process, therefore $333,232 \times 8\% = 26,659$. For the first year, HHS expects the SDR fee per arbitration to be \$25 therefore $\$25 \times 26,659 = \$666,475$.

into a more uniform and structured process. As stated earlier in this preamble, these interim final rules extend the balance billing protections related to external review to grandfathered plans. Grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Additionally, for non-grandfathered health plans these interim final rules clarify that, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review. Grandfathered and non-grandfathered plans must comply either with a state external review process or the Federal external review process. A more uniform external review process will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all affected parties. In general, the Departments expect that these interim final rules will improve the extent to which group health plans, issuers, and FEHB carriers provide benefits consistent with the established terms of individual plans or coverages. This change will cause some participants to receive benefits that they might otherwise have been denied. Furthermore, expenditures by plans may be reduced as a fuller system of claims and appeals processing helps facilitate enrollee acceptance of cost management efforts.

Furthermore, the more uniform standards for handling appeals and external review provided by these interim final rules will reduce the incidence of inappropriate denials, averting serious, avoidable lapses in access to health care and resultant injuries and losses to participants, beneficiaries, and enrollees. These changes also will enhance participants', beneficiaries', and enrollees' level of confidence in and satisfaction with their health care benefits and improve plans' awareness of participant, beneficiary, enrollee, and provider concerns. These changes could prompt plan and issuer responses that improve health care quality.

1.5. Costs

These interim final rules seek to protect patients from surprise billing, while also seeking to minimize the costs to providers, facilities, plans, issuers, and individuals.

The ultimate effect of the Federal IDR process on health care costs is

uncertain. Discussions of the uncertainty and potential transfers that the Departments expect are included in the Transfers and Uncertainty sections.

1.5.1. Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities

The Departments and OPM do not have data on how many claims will be submitted to the Federal IDR process. For the purposes of the estimates in this section, the Departments and OPM rely on the experience of New York State. In 2018, New York State had 1,014 IDR decisions, up from 650 in 2017 and 396 in 2016.¹⁸⁵ The Departments do not know what is causing the increasing trend or whether the trend is likely to continue to increase. The Departments seek comments on this trend for analytic purposes. In 2018, the state of New York accounted for 5.8 percent of the private insurance market.¹⁸⁶ For purposes of this analysis, the Departments assume that, going forward, New York State will continue to see 1,000 IDR cases each year and that the number of Federal IDR cases will be proportional to that in New York State by share of covered individuals in the private health coverage market. Accordingly, the Departments estimate that there will be approximately 17,000 claims that are submitted to the Federal IDR process each year.¹⁸⁷ The Departments seek comment on this estimate.

Surprise billing decreased by 34 percent in New York State between 2015 and 2018 when the state implemented an IDR process.¹⁸⁸ While the number of IDR cases has been trending up, the decline in surprise billing is likely to result in a decline in IDR cases. Additionally, the usage and

cost of certified IDR entities is likely to decrease when certified IDR entities use the QPA as the rebuttable presumption in payment determination, particularly after the first instance of using the QPA. The Departments do not have any data or experiences on which to base an estimate of how much use of the Federal IDR process will decline over time. Accordingly, in these estimates, prevalence of the use of the Federal IDR process is assumed to be constant; however, the Departments recognize that this is likely an overestimate.

The Departments estimate that the cost associated with the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities will be \$38.4 million. This includes an estimated cost of \$21.1 million for paperwork requirements. For more details, please refer to the Paperwork Reduction Act section of this preamble.

In addition to the paperwork costs for the Federal IDR process, the Departments estimate that it will take, a medical and health services manager 2 hours and a clerical worker 15 minutes on average to prepare materials for open negotiation for each plan, issuer, or FEHB carrier and provider or facility. The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 23,111 claims will go through open negotiation.¹⁸⁹ This results in a cost of \$10.3 million.¹⁹⁰ If the plan, issuer, or FEHB carrier and the provider or facility fail to select a certified IDR entity, the Departments will select a certified IDR entity through a random selection method. The Departments assume that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties. The Departments request comment on this assumption.

Furthermore, the party whose offer was not chosen by the certified IDR entity must pay the certified IDR entity fee, in addition to the administrative fee (required to be paid by both parties upon initiation of the IDR process). However, if the parties agreed upon an out-of-network rate, the certified IDR entity fee must be divided equally

¹⁸⁵ Adler, Loren. "Experience with New York's Arbitration Process for Surprise Out-of-Network Bills." U.S.C.-Brookings Schaeffer on Health Policy. (October 2019). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/>.

¹⁸⁶ In 2018, 10.5 million individuals had employer-sponsored insurance and 1.8 million individuals had other private coverage in New York State, while 178.4 million individuals had employer-sponsored coverage and 34.8 million individuals had other private coverage nationally. The Departments estimate that New York accounts for 5.8 percent of the private insurance market $((10.5 + 1.8)/(178.4 + 34.8) = 5.8 \text{ percent})$. See Employee Benefits Security Administration. "Health Insurance Coverage Bulletin." (March 2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

¹⁸⁷ This is calculated as: $1,000/0.058 = 17,333$.

¹⁸⁸ Marion Mass. "Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart." Morning Consult. (March 2020). <https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/>.

¹⁸⁹ This is calculated $17,333/(1 - 0.25) = 23,111$.

¹⁹⁰ The burden is estimated as follows: $23,111 \text{ claims} \times 2 \text{ hours} + 23,111 \text{ claims} \times 0.25 \text{ hour} = 51,999 \text{ hours}$. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: $23,111 \text{ claims} \times 2 \text{ hours} \times \$105.01 + 23,111 \text{ claims} \times 0.5 \text{ hour} \times \$55.23 = \$5,172,803.2 \times 2 = \$10,345,606.4$. Labor rates are EBSA estimates.

between the parties, unless otherwise agreed to by the parties. In New York, IDR entities included independent review organizations who contracted with board certified physicians and other insurance contract experts.¹⁹¹ The fees charged by IDR entities in New York ranged from \$300 to \$600.¹⁹² In Texas, the state contracted with individual attorneys to provide IDR entities. In Texas, fixed fees ranged from \$270 to \$6,000.¹⁹³ Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately \$400. This results in a cost of \$6.9 million.¹⁹⁴

1.5.2. IDR Process for Air Ambulances

In 2018, 178.4 million individuals had employer-sponsored health insurance and 34.8 million individuals had other private insurance, including individual market coverage.¹⁹⁵ In 2017, the Health Cost Institute (HCCI) estimated that, on average, there were 33.3 air ambulance uses per 100,000 people,¹⁹⁶ and the Government Accountability Office (GAO) estimated that approximately 69 percent of air transports resulted in an out-of-network bill.¹⁹⁷ The Departments do not have data on what percent of out-of-network bills will proceed to the Federal IDR process; however, given the nature of air ambulance services, the Departments assume that it will be substantially higher than for hospital or emergency department claims. The Departments assume that 10 percent of out-of-network claims for air ambulance services will be submitted to the Federal

IDR process,¹⁹⁸ which would result in nearly 4,900 air transport payment determinations in the Federal IDR process each year.¹⁹⁹ The Departments seek comment on this estimate.

The Departments estimate that the cost associated with the Federal IDR process for nonparticipating providers or nonparticipating providers of air ambulance services will be \$11.1 million. This includes an estimated cost of \$5.3 million for paperwork requirements. For more details, please refer to the Paperwork Reduction Act section.

In addition to the paperwork costs, the Departments estimate that it will take, a medical and health services manager 2 hours and a clerical worker 15 minutes on average to prepare materials for open negotiation for each plan, issuer, or FEHB carrier and provider of air ambulance services. The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 6,532 claims will go through open negotiation.²⁰⁰ This results in a cost of \$3.8 million.²⁰¹

As stated above, if the plan, issuer, or FEHB carrier, and the nonparticipating provider of air ambulance services fail to select a certified IDR entity, the Departments will select a certified IDR entity through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Furthermore, the party whose offer was not chosen by the certified IDR entity must pay the certified IDR entity fee, in addition to the administrative fee (initially required to be paid by both

parties upon initiation of the Federal IDR process). However, if the parties agree upon an out-of-network rate, the costs must be divided equally between the parties, unless otherwise agreed to by the parties. In New York, IDR entities included independent review organizations that contracted with board certified physicians and other insurance contract experts.²⁰² The fees charged by IDR entities in New York ranged from \$300 to \$600.²⁰³ In Texas, the state contracted with individual attorneys to provide IDR entities. In Texas, fixed fees per case ranged from \$270 to \$6,000.²⁰⁴ Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately \$400. This results in a cost of approximately \$2 million.²⁰⁵ This results in a cost of approximately \$2 million.²⁰⁶

1.5.3. Requests Extension of Time Periods for Extenuating Circumstances

A plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services may request an extension regarding the time periods set forth in these interim final rules, other than for the timing of the payments, including payments to the provider, facility, or air ambulance services, under extenuating circumstances. To request an extension, entities will need to submit the Request for Extension due to Extenuating Circumstances form through the Federal IDR portal, if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Additionally, they must attest that prompt action will be taken to ensure that the required action is made as soon as administratively practicable. The Departments estimate that the costs associated with requests for the extension of time periods will be \$1,381 annually. For more details, please refer to the Paperwork Reduction Act section of this preamble.

²⁰² Kaiser Family Foundation. "Surprise Medical Bills: New Protections for Consumers Take Effect in 2022." (2019). <https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/>.

²⁰³ The Commonwealth Fund. "How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payments in Surprise Billing." (February 2020). <https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise>.

²⁰⁴ Kaiser Family Foundation. "Surprise Medical Bills: New Protections for Consumers Take Effect in 2022." (2019). <https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/>.

²⁰⁵ The cost is estimated as follows: (4,899 × \$400) = \$1,959,600.

²⁰⁶ The cost is estimated as follows: (4,899 × \$400) = \$1,959,600.

¹⁹¹ Kaiser Family Foundation. "Surprise Medical Bills: New Protections for Consumers Take Effect in 2022." (2019). <https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/>.

¹⁹² The Commonwealth Fund. "How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payments in Surprise Billing." (February 2020). <https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise>.

¹⁹³ Kaiser Family Foundation. "Surprise Medical Bills: New Protections for Consumers Take Effect in 2022." (2019). <https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/>.

¹⁹⁴ The cost is estimated as follows: (17,333 × \$400) = \$6,933,200.

¹⁹⁵ Employee Benefits Security Administration. "Health Insurance Coverage Bulletin." (March 2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

¹⁹⁶ Hargraves, John and Aaron Blotchick. "Air Ambulances-10-Year Trends in Costs and Use." Health Care Cost Institute. (2019). <https://healthcostinstitute.org/emergency-room/air-ambulances-10-year-trends-in-costs-and-use>.

¹⁹⁷ Government Accountability Office. "Air Ambulance: Available Data Show Privately-Insured Patients are at Financial Risk." (2019). <https://www.gao.gov/assets/gao-19-292.pdf>.

¹⁹⁸ The Departments utilize 10 percent as an assumption to estimate the overall number of physicians billing out-of-network at least once in a year.

¹⁹⁹ The Departments estimate that of the 213.2 million individuals with employer-sponsored and other private health insurance (178.4 million individuals with employer-sponsored health insurance and 34.8 million individuals with other private insurance), there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The Departments assume that 10 percent of the out-of-network bills will end up in IDR. (213,200,000 × 0.000333 × 0.69 × 0.1 = 4,899).

²⁰⁰ This is calculated 4,899/(1 - 0.25) = 6,532.

²⁰¹ The burden is estimated as follows: 6,532 claims × 2 hours + 6,532 claims × 0.25 hour = 39,190 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 6,532 claims × 2 hours × \$105.01 + 6,532 claims × 0.5 hour × \$55.23 = \$1,895,077. 2 × \$1,895,077 = \$3,790,154. Labor rates are EBSA estimates.

1.5.4. Requirements for Certified IDR Entities

An IDR entity must be certified under standards and procedures set forth in these interim final rules and in guidance promulgated by the Departments. For each month, certified IDR entities will be required to report information on their activity to the Departments. The Departments estimate that there will be 50 entities seeking IDR certification, as discussed earlier in this analysis of economic and paperwork burdens.

The Departments estimate that the cost associated with the IDR entity certification process and reporting requirements will be \$149,616 in the first year and \$124,491 in the subsequent years. For more details, please refer to the Paperwork Reduction Act section.

1.5.5. External Review Requirements

The interim final rules require grandfathered health plans to provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. Prior to the interim final rules, the Departments estimate that there were approximately 8.1 million participants in ERISA-covered plans in the states which currently have no external review laws or whose laws do not meet the Federal minimum requirements. These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants and that there will be approximately 12,304 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external review are actually eligible to proceed to an external review.²⁰⁷ Therefore, the Departments expect that there will be about 15,942 requests for external review. The Departments estimate that the cost associated with the external review requirements for ERISA-covered plans will be \$3.3 million.

Additionally, HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-Federal governmental plans enrollees.²⁰⁸ These estimates lead to a total of 32.8 million total enrollees in individual market and non-Federal Government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a 2 percent increase in the number of out-of-networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review requirements, resulting in an adjusted total of 30.7 million participants for non-grandfathered plans and an adjusted total of 33.3 million participants for all individual market and non-Federal Government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-Federal Government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans. HHS estimates that the cost associated with the external review requirements for individual market and non-Federal Government plans will be \$241,850.

In summary, the Departments estimate that the total annual cost associated with the External Review for DOL will be \$3.3 million and the total annual cost associated with the External Review for HHS will be \$0.2 million. For more details, see the Paperwork Reduction Act section.

1.5.6. Protections for the Uninsured

These interim final rules seek to protect uninsured (or self-pay) individuals from surprise billing through two mechanisms: The provision of good faith estimates from providers and facilities and the patient-provider

dispute resolution process to resolve billing disputes when an uninsured (or self-pay) individual receives a bill for charges that are substantially in excess of the expected charges listed in the good faith estimates.

1.5.7. Good Faith Estimates

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden to convening providers or facilities to notify uninsured (or self-pay) individuals of the availability of good faith estimates to be approximately 2,743,283 hours with an equivalent cost of \$320,250,167. HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon requests between 2022 and 2024 to be \$356,727,765 and total burden hours of 3,538,305.

1.5.8. Patient-Provider Dispute Resolution Process

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and health care providers and health care facilities to be approximately 255,524 hours with an equivalent cost of \$29,764,646.

1.5.9. Patient-Provider SDR Entity Certification

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden associated with the SDR entity certification to be 16 hours with an equivalent cost of \$1,873 in the first year. In subsequent years, the total hour burden associated with the SDR entity certification or recertification is 2.25 hours with an equivalent cost of \$257. HHS seeks comment on the assumptions and calculations made in the corresponding Information Collection Request (ICR). The Departments also seek comment on the estimates presented in this section and on any additional costs incurred by patients, providers, providers of air ambulance services, facilities and uninsured (or self-pay) individuals.

1.5.10. Summary

The Departments estimate the total cost burden associated with these interim final rules to be \$760.95 million in the first year, with \$38.43 million attributable to the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities or

²⁰⁸ Individual market based on data from MLR annual report for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>. Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

²⁰⁷ North Carolina Department of Insurance. "Health Insurance Smart NC: Annual Report on External Review Activity 2013." <https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531>.

group health plans or health insurance issuers offering health insurance coverage, \$11.08 million attributable to the Federal IDR process for air ambulance services; \$149,616 attributable to costs associated with certification and recordkeeping requirements for certified IDR entities, \$4.02 million attributable to the external review process, and \$706.7 million attributable to the patient-provider dispute resolution process.

The Departments seek comment addressing the costs that will be associated with these interim final rules. The Departments also seek comment on how these interim final rules will affect individuals from minority and underserved communities, and providers and facilities who serve these individuals.

1.6. Transfers

These interim final rules will protect patients from surprise bills for emergency and nonemergency medical services and air ambulance services. The Departments and OPM recognize this as transfers between individuals, plans, issuers, FEHB carriers, and providers, facilities, and providers of air ambulance services. The Departments and OPM expect that these interim final rules will result in some transfers from providers, facilities, and providers of air ambulance services to individuals, some transfers from plans, issuers, and FEHB carriers to providers, facilities, and providers of air ambulance services, and some transfers from individuals to plans, issuers, and FEHB carriers and providers, facilities, and providers of air ambulance services. The magnitude of each of these transfers is uncertain, and as such, the ultimate effect of the Federal IDR process on each of entity is largely uncertain.

These interim final rules may result in lower out-of-pocket spending by individuals, as these interim final rules are expected to decrease surprise billing. This result would follow from two types of transfers: Transfers from providers, facilities, and providers of air ambulance services who had previously balance billed individuals for out-of-network claims to individuals who would have received those balance bills, and transfers from plans, issuers, and FEHB carriers who were previously not responsible for out-of-network bills to providers who would submit out-of-network bills to plans, issuer, and FEHB carriers as a result of these interim final rules. The Departments request comment or data on how large each of these transfers might be.

As shown in Table 3, the mean provider charges relative to Medicare

payment rates differ across physician specialties, and the ratios for specialties in which surprise billing is more common have a higher ratio of mean provider charges relative to Medicare payments rates than those specialties for which surprise billing is less common. These higher rates have been linked to the fact that patients are not able to select providers in these specialties, leaving patients more vulnerable to surprise billing.²⁰⁹ The Departments expect that the proposed interim final rules will lead to the ratio of mean provider charges to Medicare payment rates to converge with specialties with comparatively infrequent surprise billing.

TABLE 3—RATIO OF MEAN PROVIDER CHARGES TO MEDICARE PAYMENT RATES BY SPECIALTY

Specialty	Mean ratios, 2018 ²¹⁰
Specialties with infrequent surprise billing	
Family Practice	2.1
Internal Medicine	2.2
Primary Care	2.2
Dermatology	2.1
Specialties with frequent surprise billing	
Anesthesiology	7.0
Emergency Medicine	5.7
Diagnostic Radiology	4.0
Pathology	2.7

Further, research finds that New York’s Out-of-Network Law²¹¹ has saved consumers over \$400 million from the date of implementation, March 2015, through the end of 2018 with respect to emergency services alone.²¹² These savings have been realized in part through a reduction in costs associated with emergency services and an increased incentive for network participation. By establishing an IDR process for out-of-network emergency

²⁰⁹ See Hannick, Kathleen and Loren Adler. “Provider Charges Relative to Medicare Rates, 2012–2018.” USC-Brookings Schaeffer on Health Policy. (May 2021). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/05/03/provider-charges-relative-to-medicare-rates-2012-2018/>.

²¹⁰ See Hannick, Kathleen and Loren Adler. “Provider Charges Relative to Medicare Rates, 2012–2018.” USC-Brookings Schaeffer on Health Policy. (May 2021). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/05/03/provider-charges-relative-to-medicare-rates-2012-2018/>.

²¹¹ NY Fin Serv L § 605 (2014).

²¹² 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). <https://www.pacep.net/assets/documents/NYReportontheIDRProcess.pdf>.

services, the Out-of-Network Law reduced out-of-network billing by 34 percent and lowered in-network emergency physician payments by 9 percent.²¹³

The interim final rules are expected to have an effect on premiums, although there is uncertainty around how premiums will ultimately be affected. The Congressional Budget Office estimated the provisions in the No Surprises Act are likely to reduce premiums by 0.5 percent to 1 percent in most years.²¹⁴ In comparison, the CMS’s Office of the Actuary (OACT) estimated the provisions are likely to increase premiums by 0.00 percent to 0.35 percent.²¹⁵ Neither of these estimates isolate the effect attributable to the Federal IDR process.

The ultimate effect on premiums will depend on how much plans, issuers, FEHB carriers, and providers, facilities, and providers of air ambulance services will use the Federal IDR process and how the Federal IDR process affects plan, issuer, and FEHB carrier liability. If payments to providers decrease, this change may result in a decrease in premiums. This decrease in premiums will result in a transfer from providers and facilities to participants, enrollees, or beneficiaries through plans, issuers, and FEHB carriers. Additionally, this could result in a transfer from eligible enrollees to the Federal Government in the form of reduced payment of the Premium Tax Credits (PTC). Conversely, if payments to providers increase, the expenditures for plans, issuers, and FEHB carriers may be passed on to consumers in the form of increased premiums. This could result in three types of transfers: (1) From the participants, enrollees, and beneficiaries to the plans, issuers, and FEHB carriers; (2) from the Federal Government to

²¹³ Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. “Surprise! Out-Of-Network Billing for Emergency Care in the United States.” 128 Journal of Political Economy 9. (2020).

²¹⁴ Congressional Budget Office. “Estimate for Divisions O Through FF. H.R. 133, Consolidated Appropriations Act, 2021. Public Law 116–260.” https://www.cbo.gov/system/files/2021-01/PL_116-260_div%20O-FF.pdf.

²¹⁵ The OACT analysis assumed that an individuals’ cost-sharing is limited to their in-network cost-sharing amounts and that plans and issuers are responsible for any excess of the allowed amounts for nonparticipating providers over in-network reimbursement rates. OACT assumed that the average allowed amounts for services provided by nonparticipating providers will remain higher than in-network reimbursement rates after the No Surprises Act takes effect. OACT estimated a range of values for out-of-network allowed charges between 125 percent and 150 percent of average network rates. OACT assumed that these estimated levels reflected the Federal IDR process but did not make any explicit assumptions about the separate impact of the Federal IDR process.

eligible enrollees in the form of increased PTC; and (3) from insured individuals who pay premiums to individuals with large out-of-network bills.

In addition, these interim final rules may affect in-network and out-of-network rates received by physicians. It is possible that the out-of-network rates collected by some providers, facilities, and providers of air ambulance services will be lower than they would have been if not for the provisions in these interim final rules. There is also uncertainty around how these interim final rules will affect the negotiation dynamics between providers, facilities, plans, issuers, and FEHB carriers regarding health care costs.

As evidenced in states where arbitrators are directed to base their determinations on billed charges, there have been increased health care costs as a result of the out-of-network payment standard being higher than that in-network rate.²¹⁶ However, as noted in an analysis by the USC-Brookings Schaeffer Initiative for Health Policy, if certified IDR entities base their determinations on median in-network rates, which are typically lower than billed charges, the IDR process could place downward pressure on health care costs and premiums. If certified IDR entities choose amounts that are above median in-network rates, this could result in a potential increase in costs and premiums.²¹⁷ For example, in New York, providers prevailed in IDR at nearly twice the rate that issuers prevailed. In the state, arbiters are told to consider the 80th percentile of billed charges in their decision process. A study found that even when deciding in favor of health plans, arbitrations averaged just 11 percent below the 80th percentile of charges, which is consistently above the typical in-network or out-of-network rates. This result implies that plans, issuers, and FEHB carriers only won in arbitration when paying above-market rates.²¹⁸

²¹⁶ Ollove, Michael. *Laws to Curb Surprise Medical Bills Might Be Inflating Health Care Costs*. PEW. (2021). <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/05/20/laws-to-curb-surprise-medical-bills-might-be-inflating-health-care-costs>.

²¹⁷ Adler, Loren, et al. "Understanding the No Surprises Act." USC-Brookings Schaeffer on Health Policy. (2021). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/04/understanding-the-no-surprises-act/>.

²¹⁸ Adler, Loren. "Experience with New York's Arbitration Process for Surprise Out-of-Network Bills." USC-Brookings Schaeffer on Health Policy. (October 2019). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/>.

Further, in the Federal IDR process, certified IDR entities are required to consider credible information about additional factors such as providers' expertise and patient characteristics after beginning with a presumption in favor of the QPA, making it beneficial for a provider or facility to initiate the process when they expect to be paid more than the median in-network rate. A report from the Congressional Budget Office noted that some providers, particularly those with more specialized services, may be able to negotiate for larger payments from insurers by threatening to initiate the Federal IDR process.²¹⁹ This outcome could result in a transfer from plans, issuers, and FEHB carriers to providers. Furthermore, this outcome could also result in higher premiums, which could ultimately result in a transfer from patients to providers.²²⁰

In addition, these interim final rules may affect provider and facility payments and revenue. It is possible that the payments collected by some providers and facilities will be lower than they would have been if not for the provisions in these interim final rules. These interim final rules set standards requiring certified IDR entities to consider the QPA (typically the median in-network rate) when making payment determinations; the Departments expect this approach to have a downward impact on health care costs, potentially resulting in transfers from providers and facilities to individuals with health coverage.

Furthermore, the external review requirements of these interim final rules may result in a transfer from plans, or issuers to participants and beneficiaries now receiving payment for denied benefits. These transfers will improve equity, because incorrectly denied benefits will be paid.

These interim final rules also establish requirements for the uninsured (or self-pay) individual to submit an administrative fee payment when initiating the patient-provider dispute resolution process as provided in 45 CFR 149.620(g) and described in section IV.B.8 of this preamble. This requirement may result in a transfer to the uninsured (or self-pay) individual from the provider or issuer if the uninsured (or self-pay) individual prevails in the dispute resolution

process. Under such circumstances, the SDR entity must apply a reduction equal to the administrative fee amount paid by the individual to the final determination amount for charges to be paid by the individual for the items or services.

1.7. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation. The Departments considered whether the certified IDR entity was required to consider the QPA and permitted to consider other statutory factors only when a party presents clear and convincing evidence that the value of the qualified IDR item or service materially differs from the QPA due to those factors, or whether the certified IDR entity should be required to consider all factors equally.

The Departments are of the view, however, that applying a clear and convincing evidence standard does not afford enough weight to the statutory requirement that certified IDR entities consider the additional permissible factors. Such a standard could result in a certified IDR entity failing to consider credible information a party provides, even where it clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. On the other hand, permitting consideration of all permissible factors equally disregards the weight that the No Surprises Act places on the QPA. For example, Code section 9816(c)(7)(B)(iii)-(iv), ERISA section 716(c)(7)(B)(iii)-(iv), and PHS Act section 2799A-1(c)(7)(B)(iii)-(iv) require the Departments to report the offers as a percentage of the QPA and the amount of the offer selected, expressed as a percentage of the QPA. The statute also provides strict rules for calculating the QPA and creates disclosure and audit requirements regarding the QPA.

The Departments, therefore, are of the view that starting with a rebuttable presumption that the QPA is the appropriate payment amount properly emphasizes the QPA while requiring the consideration of the permissible additional factors when appropriate. The QPA generally is based on the median of contracted rates, which are the product of contract negotiations between providers and facilities and plans (and their service providers) and issuers, and therefore generally reflect market rates. The statute sets out detailed rules for calculating the QPA, including a requirement that when

²¹⁹ Congressional Budget Office Cost Estimate. "H.R. 2328, Reauthorizing and Extending America's Community Health Act." (September 2019). <https://www.cbo.gov/system/files/2019-09/hr2328.pdf>.

²²⁰ Congressional Budget Office Cost Estimate. "H.R. 2328, Reauthorizing and Extending America's Community Health Act." (September 2019). <https://www.cbo.gov/system/files/2019-09/hr2328.pdf>.

plans, issuers, and FEHB carriers do not have sufficient information to calculate their own median contracted rates, they utilize a database free of conflicts of interests.²²¹ Plans, issuers, and FEHB carriers must provide specific information on how the QPA is calculated to nonparticipating providers and facilities, ensuring that they are aware of how this rate was calculated.²²² Plans, issuers, and FEHB carriers are also subject to audit requirements that will be enforced by the Departments and OPM to ensure that they follow these standards.²²³ The Departments are also required to report how the out-of-network rates compare to the QPA, suggesting that Congress saw it as an appropriate analogue for the out-of-network rate.²²⁴ Moreover, starting with the QPA as the rebuttable presumption for the appropriate payment amount will increase the predictability of dispute resolution outcomes which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, the Departments are of the view that this approach will protect participants, beneficiaries, and enrollees from excessive costs, either through reduced costs for items and services or through decreased premiums. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must begin with the presumption that the QPA for the applicable year is the appropriate payment amount for the qualified IDR items or services. The certified IDR entity must, however, consider the other factors when a party provides credible information, and must choose the offer closest to the QPA, unless the credible evidence submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.

As noted previously, emphasizing the QPA will allow for predictability. As mentioned earlier in this preamble, when the recognized amount is the QPA, plans, issuers, and FEHB carriers must provide the QPA to providers and facilities when submitting an initial

payment amount or denial of payment, and must provide additional information regarding the QPA upon request. Thus, even before beginning negotiations, all parties involved will know that the QPA is the primary factor that the certified IDR entity will always consider (while other factors may be considered, depending on the circumstances). This certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor. This certainty may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period. Finally, it is anticipated that focusing on the QPA will help mitigate costs and reduce government expenditures once the Federal IDR process is fully implemented, as projected by the Congressional Budget Office.²²⁵ Therefore, after carefully considering both interpretations, the Departments chose to emphasize the QPA.

Furthermore, as discussed earlier in this preamble, the Departments considered how to select a certified IDR entity if the parties fail to do so. Academic literature is inconclusive regarding whether the selection process of an arbitrator has an effect on the arbitration results. One study found significant consistency between factors affecting an arbitrator's decision,²²⁶ suggesting that the selection of a certified IDR entity by parties to the IDR, or the selection process of a certified IDR entity by the government if the parties fail to select a certified IDR entity, should not have a significant effect on the outcome. Contrarily, another study found large differences among arbitrator decisions; however, the authors attributed these differences to information disparities between parties.²²⁷ As the parties in the Federal IDR process under these interim final rules are all professionals with specialized knowledge in health care, these information disparities are

expected to be minimal in the context of the Federal IDR process.

Although the academic literature suggests that the selection of an IDR entity is unlikely to have a significant effect on the IDR entity's determination, the Departments explored options to minimize this risk. The Departments considered alternative approaches, including whether the Departments should consider the specific fee of the certified IDR entity, or look to other factors, such as how often the certified IDR entity chooses the amount closest to the QPA. However, looking to how often the certified IDR entity chooses the amount closest to the QPA could unfairly penalize certified IDR entities that have correctly handled decisions when there is credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate. Using this as a factor in assigning certified IDR entities could incentivize decisions that do not adequately take into account the other factors set forth in the statute and these interim final rules, even when there is credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate. Moreover, the consideration of other factors may encourage plans, issuers, FEHB carriers, or providers and facilities, to decline to agree to a particular certified IDR entity, thinking that the Departments will favor certain criteria. Given the cost controls applicable to the certification process, it is unlikely that the cost of a specific certified IDR entity will be a significant factor in the inability of the parties to choose a certified IDR entity.

Thus, after carefully considering the alternatives, the Departments have chosen to use a random selection method to select a certified IDR entity with a fee within the allowed range. If there is an insufficient number of certified IDR entities with a fee within the allowed range available to arbitrate the case, the Departments will use a random selection method to select a certified IDR entity that has received approval from the Departments to charge a fee outside of the allowed range.

External Review

The Departments considered different amendments to the regulations for external review to address the scope for non-grandfathered plans and issuers in light of section 110 of the No Surprises Act. Under the existing rules, a claim is eligible for external review under the Federal external review process if it involves medical judgement. The Departments note that the scope of

²²¹ Code section 9816(a)(2), (3)(E); ERISA section 716(a)(2), (3)(E) and PHS Act section 2799A-1(a)(92), (3)(E); 26 CFR 54.9816-6T, 29 CFR 2590.716-6, and 45 CFR 149.140.

²²² *Id.*

²²³ 86 FR 36872, 36899 (July 13, 2021).

²²⁴ Code section 9816(c)(7)(A)(v), (B)(iii) and (iv); ERISA section 716(c)(7)(A)(v), (B)(iii) and (iv); and PHS Act section 2799A-1(c)(7)(A)(v), (B)(iii) and (iv).

²²⁵ Congressional Budget Office, Estimate for Divisions O Through FF, H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260, Enacted on December 27, 2020. <https://www.cbo.gov/publication/56962>.

²²⁶ Farber, Henry and Max Bazerman. "The General Basis of Arbitrator Behavior: An Empirical Analysis of Conventional and Final-Offer Arbitration." *The Econometric Society*, Vol. 54(4) (July 1986). <https://www.jstor.org/stable/1912838>.

²²⁷ Egan, Mark, Gregor Matvos, and Amit Seru. "Arbitration with Uniformed Consumers." National Bureau of Economic Research. (October 2018). https://www.nber.org/system/files/working_papers/w25150/w25150.pdf.

claims that are eligible for external review in general is broad, as many adverse benefit determinations involve medical judgment. The examples the Departments have provided of questions involving medical judgment (described in more detail earlier in the preamble) include questions involving health care setting, level of care, or effectiveness of a covered benefit, whether treatment involved “emergency care” or “urgent care,” affecting coverage, and how a claim is coded. The Departments note that the state external review process also extends to questions involving the requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Departments are of the view that many claims that result in an adverse benefit determination involving items and services subject to the surprise billing and cost-sharing protections under the No Surprises Act generally would be eligible for external review under the current scope as specified in the 2015 final regulations. However, as stated above, section 110 of the No Surprises Act directs the Departments to require the external review process under PHS Act section 2719 to apply with respect to *any* adverse determination by a plan or issuer under PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817, including with respect to whether an item or service that is subject to such a determination is an item or service to which the respective section applies. The Departments are of the view that it is important to ensure that consumers can avail themselves of external review in these situations and ensure that they are afforded full protection against surprise medical costs (including cost sharing), as intended by the No Surprises Act. Accordingly, these interim final rules amend the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review.

HHS considered certain other approaches to furnishing good faith estimates to uninsured (or self-pay) individuals. HHS considered notification of the availability of good faith estimates using only broad outreach efforts and not, in addition to, specifically requiring that providers or facilities inform uninsured (or self-pay)

individuals of the availability of good faith estimates. However, HHS is of the view that uninsured (or self-pay) individuals are more acutely aware of and concerned about health care costs when engaging with providers and facilities. Not requiring providers or facilities to notify uninsured (or self-pay) individuals of the availability of good faith estimates would potentially deprive uninsured (or self-pay) individuals of the ability to avail themselves of these important consumer protections under the No Surprises Act.

HHS considered requiring good faith estimates for each instance of a recurring item or service with the same expected charges. HHS is of the view that to do so would unnecessarily increase the burden on providers and facilities, particularly for those items and services furnished weekly or more than once per week, without adding additional informational value for the uninsured (or self-pay) individual. HHS is of the view that, while a single good faith estimate for certain recurring items and services is sufficient, establishing certain limitations is necessary in order to confirm and periodically evaluate the accuracy of the information included in the good faith estimate. For instance, HHS includes requirements that limit the applicability of a good faith estimate for recurring items and services to no longer than 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months, a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate.

HHS also considered requiring the use of standardized notices for good faith estimates issued to uninsured (or self-pay) individuals. However, HHS is of the view that requiring the use of such model notices for good faith estimates would not allow providers or facilities necessary flexibilities to develop notices that would be most effective for their patient populations.

HHS also considered basing the substantially in excess threshold as equal to only a percentage of the expected charges in the good faith estimate; however HHS has concerns that such an approach could make dispute resolution easier to access for items or services where the expected charges are small, which would include circumstances where the difference between the billed charge and the expected charges in the good faith estimate is too small to justify the costs of dispute resolution. Alternatively, when the total expected charges in the good faith estimate are very high, few items or services could be subject to

dispute resolution, despite significant unexpected charges. HHS also considered other approaches to defining the “substantially in excess” standard, including setting it as the lesser of a specific percentage of the total expected charges in the good faith estimate or a flat maximum dollar amount, or based on a percentage of the expected charges in the good faith estimate that varies depending on the expected costs of the items or service. Although these approaches would mitigate some of the concerns discussed previously and would make it easier for higher cost items or services to meet the substantially in excess threshold, these approaches would increase concerns that dispute resolution for lower cost services could be overused, thus potentially increasing costs for providers and facilities and potentially increasing costs for such items or services. As an alternative, HHS also considered an approach for determining “substantially in excess” based on an amount that is the greater of either a percentage of the total amount of expected charges in the good faith estimate or a flat minimum dollar amount. However, HHS remains concerned that such an approach could effectively put dispute resolution out of reach for uninsured (or self-pay) individuals in situations where the expected charges for the item or service are high, particularly for those who need to undergo more complex procedures. Finally, HHS considered a tiered approach, either a flat dollar amount that would increase as the total expected charges in the good faith estimate increases or a percentage that would decrease as the total of expected charges in the good faith estimate increases, but HHS is of the view that such an approach would add undue complexity and could be confusing for uninsured (or self-pay) individuals, providers, facilities, and other stakeholders.

Lastly, HHS considered basing the definition of “substantially in excess” on billed charges that exceed a certain percentage for the same or similar services using an independent database. However, HHS is of the view that such a mechanism is inconsistent with the statute which contemplates items or services to be determined to be “substantially in excess” based on the good faith estimate provided, rather than being based on a specific benchmark, such as that provided by an independent database.

As HHS obtains additional experience with the patient-provider dispute resolution process, HHS intends to review data on the use of the dispute

resolution process and may propose adjustments to the definition of “substantially in excess” in the future.

HHS considered whether to base eligibility for patient-provider dispute resolution on whether an individual item or service listed on a good faith estimate is billed an amount substantially in excess to the expected charge in the good faith estimate. However, HHS is concerned that such an approach would add complexity as each item or service on the good faith estimate would need to be assessed separately for eligibility. HHS also considered basing the eligibility on the total of all billed charges for all items or services and all providers or facilities listed on the good faith estimate, however such an approach would be significantly more complex given that the good faith estimate could consist of estimates of multiple providers and facilities who would bill the uninsured (or self-pay) individual separately. This approach could also potentially increase the burden on the uninsured (or-self pay) individual who would likely need to submit multiple bills from multiple providers or facilities for dispute resolution. Additionally, such an approach could require a provider or facility to respond to a notice requesting additional documentation from an SDR entity due to the billing of other providers, even when the provider or facility did not bill an uninsured (or self-pay) individual an amount substantially in excess of the good faith estimate. As a result, HHS is of the view that it is appropriate to base eligibility for dispute resolution on each provider or facility listed on the good faith estimate.

HHS considered not requiring co-providers or co-facilities that are not represented on a good faith estimate due to replacing an original co-provider or co-facility that was represented in a good faith estimate to be subject to the patient-provider dispute resolution process due to not having provided estimates of expected charges with which to base whether the billed charges substantially exceed the estimate. However, HHS is of the view that such requirements should still apply in these circumstances as they provide important consumer protections that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills, and allowing a replacement co-provider or co-facility to essentially circumvent these protections simply due to not being directly represented on the good faith estimate would weaken these consumer protections.

HHS considered requiring the Federal IDR portal be used by an uninsured (or self-pay) individual to initiate a patient-provider dispute resolution process rather than making the use of the Federal IDR portal optional. However, HHS was concerned that such a requirement could pose an unreasonable barrier for uninsured (or self-pay) individuals, particularly those with limited or no access to the internet.

HHS considered not providing a mechanism for the uninsured (or self-pay) individual to settle on a payment amount for an item or service prior to an SDR entity issuing a payment determination. However, HHS is of the view that providing an opportunity for the uninsured (or self-pay) individual and the provider or facility to come to terms on a payment amount that is mutually agreeable for the parties involved is appropriate as it can help resolve payment disputes quickly without the need for a determination by an SDR entity. Such a process can also incentivize a provider or facility to accept a lower payment amount or to provide financial assistance to the uninsured (or self-pay) individual.

HHS considered whether to allow the SDR entity to have discretion to determine a payment amount lower than the expected charges listed in the good faith estimate. However, HHS is of the view that such an approach would result in less transparency and predictability for the uninsured (or self-pay) individuals, providers and facilities regarding the outcomes of the patient-provider dispute resolution process. Therefore, HHS is of the view that the good faith estimate represents charges the uninsured (or self-pay) individual would likely expect to pay for the items or services, and as a result the consumer protections established in the patient-provider dispute resolution process serve as an important backstop that protects an uninsured (or self-pay) individual from unexpected billed charges that substantially exceed the good faith estimate.

HHS considered allowing an SDR entity to use a different standard for conducting determinations, other than that the information submitted by the provider must provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. However, HHS is of the view is that such an approach

would not align with the standard utilized in the Federal IDR processes discussed in section III of this preamble. This approach would result in adding undue complexity to the patient-provider dispute resolution process and the use of a different standard from the Federal IDR process could potentially lead to confusion for uninsured (or self-pay) individuals, providers and facilities.

When an SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, HHS considered requiring that the SDR determine that the payment amount be equal to the billed charge, rather than the lesser of the billed charge or the payment amount for the same or similar services contained on an independent database (or if applicable, the good faith estimate). However, HHS is concerned that such an approach may increase the incentive for providers and facilities to inflate their billed charges, particularly in cases where the provider or facility believes they can justify the billed charges.

HHS considered not requiring an SDR entity determination to be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved. However, HHS was concerned that not having the process be binding could lead to a provider or facility not abiding by the SDR entity determination and holding the uninsured (or self-pay) individual liable for the entire billed charge even if the SDR entity determined that the uninsured (or self-pay) individual pay a lower amount. HHS is of the view that without making the determination binding, the consumer protections established in PHS Act section 2799B-7 would be significantly diminished and that the cost for administering the program may outweigh the benefit.

HHS considered various approaches to paying for the costs of the patient-provider dispute resolution process. HHS considered requiring the uninsured (or self-pay) individual to pay the patient-provider dispute resolution costs (e.g., SDR entity costs) in cases where the individual does not prevail in dispute resolution. However, such an approach could place a significant burden on the uninsured (or

self-pay) individuals, especially low-income individuals. Such a requirement would also not be in alignment with the requirements in PHS Act section 2799B-7 that the administrative fee be set so as not to create a burden to participation. HHS also considered requiring the provider or facility to pay for dispute resolution costs when the provider or facility does not prevail. However, HHS has concerns that such an approach would impose a burden on the providers and facilities and could potentially provide an incentive for the providers and facilities to increase the prices on uninsured (or self-pay) individuals to account for potential patient-provider dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether.

HHS considered using an open certification process for SDR entities rather than contracting with a limited number of SDR entities that meet the certification requirements outlined in 45 CFR 149.620(d). However, HHS is of the view that an open certification process would increase the administrative burden associated with certifying SDR entities and would not allow for the same level of administrative oversight, monitoring, and audit potential as opposed to contracting with the SDR entities directly.

HHS considered not providing a mechanism to defer to a state that implements a parallel patient-provider dispute resolution process that meets certain minimum Federal requirements. However, such an approach would not allow for states to establish processes which meet Federal minimum standards that are specifically tailored for the state's residents and providers and facilities in the state. Allowing a state to establish a process that meets or exceeds the Federal minimum standards is also consistent with other provisions of the No Surprises Act such as allowing the application of a state law to determine the total amount payable to out-of-network providers and facilities.

1.8. Uncertainty

It is unclear what percentage of participants, beneficiaries, and enrollees experience surprise billing. The frequency of surprise billing may differ among small and large health issuers.

Furthermore, among individuals who experience surprise billing, the percentage of claims that would be resolved by the Federal IDR process is unclear. It is possible that some claims would be resolved through early settlement before they proceed to the Federal IDR process. It is also possible that some claims would be determined to be ineligible for the Federal IDR

process. While there is some data from New York regarding these questions, it is uncertain whether other states' trends will be similar to New York's or whether New York's experience can be extrapolated to other states.

Additionally, these interim final rules permit multiple qualified IDR items and services to be batched in a single payment determination to encourage efficiency. In order for qualified IDR items or services to be batched, they must involve the same service code or comparable code under different procedural systems. Batching by service code will allow parties to group together qualified IDR items and services that are medically similar, promoting efficiency by allowing the certified IDR entity to consider similar qualified IDR items and services, and more efficiently focus on where the value of the qualified IDR items or services is consistently materially different from the QPA. Additionally, the Departments require batching to be done by provider or group of providers, the same facility, or the same provider of air ambulance services sharing the same NPI or TIN. By allowing groupings of providers with the same TIN, this will allow group practices to batch together qualified IDR items or services. Due to the uncertainty surrounding how often and how many payment determinations will consider batched items and services, the Departments acknowledge the high degree of uncertainty around the estimates of how many disputes will result in the Federal IDR process each year.

Additionally, it is unclear how these interim final rules will alter the experiences of everyone involved in the health care system, beyond the individuals and entities that are involved in the Federal IDR process. For example, research finds that New York's Out-of-Network law²²⁸ reduced surprise billing by 34 percent and lowered in-network emergency physician payments by 9 percent via shifting the billing costs to emergency department physicians who bill on an out-of-network basis.²²⁹ Research also finds that New York's Out-of-Network law increased the incentive for physicians providing emergency services to participate in health plan networks.²³⁰

²²⁸ NY Fin Serv L § 605 (2014).

²²⁹ 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>.

²³⁰ 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). <https://www.pacep.net/assets/documents/NYReportontheIDRProcess.pdf>.

It is unclear to what degree providers and facilities may adjust their pricing for items and services in order to pay for the anticipated costs of providing a good faith estimate. It also is unclear if providers and facilities will provide higher estimates than the amounts they intend to charge in order to avoid the patient-provider dispute resolution process, and what impact this practice might have on an individual's decision to seek necessary care. For example, some providers and facilities may overestimate the costs for items or services, up-code to a more expensive service, or add additional unnecessary services, which could circumvent the intended consumer protections. These actions could impact whether some patients defer or delay needed care on the basis of perceived costs or have a pathway to dispute bills through the patient-provider dispute resolution process.

Among uninsured (or self-pay) individuals who receive billed charges that are substantially in excess of the expected charges in the good faith estimate, it is unclear to what extent such bills will be resolved using the patient-provider dispute resolution process, or to what extent such bills will be resolved in other ways such as a settlement where the provider or facility would offer a lower bill, discount, or an offer of financial assistance.≤

Last, the Departments are uncertain whether the policies adopted in these interim final rules could ultimately lead to inflation of health care costs or could result in a reduction in uninsured (or self-pay) individuals' access to needed care. One study, which examined the arbitration decisions in New Jersey, where billed charges or usual and customary rates are taken into consideration in the IDR process, found that the median payments awarded were 5.7 times higher than the median in-network rates for the same services. The study concluded that basing arbitration decisions on provider-billed charges would likely increase health care costs.²³¹ In New York State, state guidance directs arbiters to consider the 80th percentile of billed charges and the New York Department of Financial Services has found that arbitration decisions resulted in, on average, charges 8 percent higher than the

²³¹ Chartock, B.L., Adler, L., Ly, B., Duffy, E., & Trish, E. (2021). Arbitration over Out-Of-Network Medical Bills: Evidence from New Jersey Payment Disputes: Study Examines Arbitration Decisions to Resolve Payment Disputes Between Issuers and Out-Of-Network Providers in New Jersey. 40 *Health Affairs* 1, 130–137. <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.00217>.

eightieth percentile of billed charges.²³² By considering the offer closest to the QPA and prohibiting certified IDR entities from considering billed charges, these interim final rules will likely limit potential inflationary effects even if arbitration leads to payment determinations that are above the amounts plans and issuers typically pay to in-network providers.²³³ Thus, these interim final rules may constrain inflationary effects, but the degree to which they may do so is uncertain.

1.9. Conclusion and Summary of Economic Impacts

The Departments are of the view that these interim final rules will help ensure that consumers are protected from unexpected out-of-network medical costs by creating a process for plans, issuers, FEHB carriers and nonparticipating providers, facilities, and providers of air ambulance services to resolve disputes regarding out-of-network rates. These interim final rules provide a market-based approach that will allow these entities to agree upon reasonable payment rates.

The Departments expect a significant reduction in the incidence of surprise billing, potentially resulting in significant savings for consumers. There may be a potential transfer from providers, facilities, and providers of air ambulance services 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. Overall, these interim final rules provide a mechanism to effectively resolve disputes between plans, issuers, and FEHB carriers and providers and facilities, while protecting patients.

HHS is of the view that the provisions in these interim final rules will protect uninsured (or self-pay) individuals from surprise medical costs by allowing them to obtain a good faith estimate of expected charges from providers and facilities prior to receiving scheduled items and services and upon request. With this information, uninsured (or self-pay) individuals may be more likely

to consider and compare costs across providers or facilities prior to or upon scheduling an item or service to help inform decisions regarding costs for an item or service. These benefits, however, are predicated on the good faith estimate being a reasonably predictive and accurate document that can be understood by patients and their representatives. Additionally, these interim final rules protect these uninsured (or self-pay) individuals by allowing an uninsured (or self-pay) individual to seek a determination through the patient-provider dispute resolution process if actual billed charges for items or services from a provider or facility are substantially in excess of the expected charges listed in the good faith estimate. Moreover, HHS is of the view that uninsured (or self-pay consumers) will also benefit from being able to take advantage of the patient-provider dispute resolution process as an intermediary step in resolving outstanding medical bills, which will delay providers sending these outstanding bills to collection agencies.

The patient-provider dispute resolution process further protects uninsured (or self-pay) individuals as the process may result in lower payments if an SDR entity determines that information submitted by a provider or facility does not provide credible information that the billed charge for an item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, in which case the SDR entity must determine as the payment amount the expected charge for the item or service (or in the case of a new item or service, \$0) to be paid by the uninsured (or self-pay) individual to the provider or facility.

The Departments estimate that these interim final rules will impose incremental costs of approximately \$760.95 million in the first year and \$440.67 million in subsequent years. Over 10 years, the associated costs will be approximately \$3.62 billion with an annualized cost of \$517.12 million, using a 7 percent discount rate.²³⁴

C. Paperwork Reduction Act

Contemporaneously with the publication of these interim final rules, the Departments are each submitting a request for a new ICR containing the information collection requirements for

the Federal IDR process, and the patient-provider dispute resolution process for HHS, created by the No Surprises Act be processed as an Emergency Clearance Request in accordance with section 5 CFR 1320.13 of the Paperwork Reduction Act, Emergency Processing. The Departments and OPM 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. 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. To obtain a copy of the ICR go to <https://www.RegInfo.gov>.

The Departments will be requesting approval of the emergency review requests by the effective date of the interim final rules. The Departments will be seeking approval of the ICRs for 180 days, the maximum allowed for an ICR approved using an emergency review. As part of the emergency review request, the Departments will be requesting that OMB waive the notice requirement set forth in 5 CFR 1320.13(d). Once the emergency submission is approved, the Departments will initiate an ICR Revision, the process required under the PRA to seek up to three (3) years of approval for the information collections. As part of the process, the Departments and OPM will open a 60-day and 30-day comment period for each ICR.

The Departments are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the Departments, including whether the information will have practical utility;
- Evaluate the accuracy of the Departments' estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example permitting electronically delivered responses).

²³² Adler, Loren. "Experience with New York's Arbitration Process for Surprise Out-of-Network Bills." U.S.C.-Brookings Schaeffer on Health Policy. (October 2019). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/>.

²³³ Fielder, Matthew, Loren Adler, and Benedic Ippolito. "Recommendations for Implementing the No Surprises Act." U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/>.

²³⁴ The costs would be \$4.19 billion over 10-year period with an annualized cost of \$491.44 million, applying a 3 percent discount rate.

Comments on these topics may also be submitted to the Departments during the open comment period for these

interim final rules. See the **ADDRESSES** section in this rule on where to send comments.

1. Labor Cost Estimates

1. Labor Cost Estimates

TABLE 4—WAGE ESTIMATES

Occupation title	Occupational code	Hourly total compensation (\$/hour)	Overhead cost (\$/hour)	Total hourly labor costs (\$/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	\$28.96	\$26.27	\$55.23
Lawyer	23-1011	105.28	35.68	140.96
Computer Programmers	15-1251	67.62	46.15	113.77
Medical Secretaries and Administrative Assistants	43-6013	27.94	18.13	46.07
Human Resources Specialists	13-1071	49.09	42.74	91.83
Business Operations Specialist	13-1198	59.60	41.72	101.32
General and Operations Manager	11-1021	88.25	34.30	122.55
Compensation and Benefits Manager	11-3111	96.97	24.81	121.78
Computer and Information Systems Managers	11-3021	113.52	53.38	166.90
Medical and Health Services Manager	11-9110	83.39	21.62	105.01
Physician (all other)	29-1228	154.74	14.66	169.40
All occupations	00-0000	39.40	24.92	64.32

Group health plans, health insurance issuers, and FEHB carriers are responsible for ensuring compliance with these interim final rules. Accordingly, in the following ICR sections, the Departments refer to costs on plans, issuers, and FEHB carriers. However, it is expected that most self-insured group health plans will work with a TPA to meet the requirements of these interim rules. The Departments recognize the potential that some of the largest self-insured plans may seek to meet the requirements of these interim final rules in house and not use a TPA or other third party, in such cases those plans will incur the estimated burden and cost directly.

2. ICRs Regarding IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities (26 CFR 54.9816-8T, 29 CFR 2590.716-8, and 45 CFR 149.510)

As discussed in the Regulatory Impact Analysis, the Departments estimate that 17,333 claims will be submitted as part of the Federal IDR process each year.

The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 23,111 claims will go through open negotiation.²³⁵ The Departments estimate that it will take, on average, a medical and health services manager 2 hours to write each notice of open negotiation and a clerical worker 15 minutes to prepare and send

the notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. As shown in Table 5, for all 23,111 payment determinations subject to these interim final rules proceeding through the Federal IDR process, the annual burden would be 51,999 hours, with an associated equivalent cost of \$5.2 million.²³⁶ The open negotiation notice must be sent within 30 business days beginning on the day the provider or facility receives an initial payment or a notice of denial of payment from the plan or issuer regarding such item or service. The Departments assume that 5 percent of these notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$693.²³⁷

TABLE 5—ANNUAL BURDEN AND COSTS TO PREPARE AND SEND THE NOTICE OF OPEN NEGOTIATION PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing costs	Total estimated cost
23,111	51,999	\$5,172,803	\$693	\$5,173,496

²³⁵ This is calculated 17,333/(1 - 0.25) = 23,111.

²³⁶ The burden is estimated as follows: 23,111 claims × 2 hours + 23,111 claims × 0.25 hour = 51,999 hours. A labor rate of \$105.01 is used for a

medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 23,111 claims × 2 hours × \$105.01 + 23,111 claims

× 0.5 hour × \$55.23 = \$5,172,803. Labor rates are EBSA estimates.

²³⁷ This is calculated 23,111 × 0.05 × (\$0.05 + \$0.55) = \$693.

The Departments estimate that it will take 2 hours for a legal professional to write the Notice of IDR Initiation and 15 minutes for a clerical worker to prepare and send the initiating notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. As shown in Table 6, for the 17,333

claims initiating the Federal IDR process, the annual burden would be 38,999 hours, with an annual equivalent cost estimate of \$3.9 million.²³⁸ The initiating party may furnish the Notice of IDR Initiation to the other party electronically if the initiating party has a good faith belief that the electronic method is readily accessible by the

other party and the notice is provided in paper form free of charge upon request; the Departments assume that these notices 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$520.²³⁹

TABLE 6—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF IDR INITIATION FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
17,333	38,999	\$3,879,602	\$520	\$3,880,122

If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing notice to the Departments of initiation of the Federal IDR process, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically through the Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no

later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties. The Departments assume that 1 percent of IDR payment determinations will be resolved by an agreement on an out-of-network rate after the Federal IDR process has been initiated. The Departments request comment on this assumption. The Departments estimate that it will take,

on average, a medical and health services manager 30 minutes to write each notice of open negotiation and a clerical worker 15 minutes to submit the notice to the Federal IDR portal. The burden for each plan, issuer, and FEHB carrier would be 45 minutes, with an equivalent cost of approximately \$66. As shown in Table 7, for the 173 payment determinations resolved in this manner, the annual burden would be 130 hours, with an associated equivalent cost of \$11,472.²⁴⁰

TABLE 7—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF AGREEMENT ON AN OUT-OF-NETWORK RATE STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
173	130	\$11,472	\$0	\$11,472

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility select a certified IDR entity, or if they fail to select a certified IDR entity, they must notify the Departments of their selection no later than 1 business day after such selection or failure to select. To the extent the non-initiating party does not believe that the Federal IDR process applies, the non-initiating party must also provide information that demonstrates the lack of applicability by

the same date that the notice of selection or failure to select must be submitted.

The Departments estimate that in 75 percent of IDR payment determinations, a certified IDR entity will be selected by the disputing parties. The Departments request comments on this assumption. Additionally, the Departments assume that it will take 1 hour for a legal professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier

would be 1.25 hours, with an equivalent cost of approximately \$119. As shown in Table 8, for the 13,000 claims that will have a certified IDR entity selected by the disputing parties, the annual burden would be 16,250 hours, with an annual equivalent cost estimate of \$1.5 million.²⁴¹ The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$390.²⁴²

²³⁸ The burden is estimated as follows: 17,333 claims × 2 hours + 17,333 claims × 0.25 hours = 38,999 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 17,333 claims × 0.25 hours × \$105.01 + 17,333 claims × 2 hours × \$55.23 = \$3,879,602. Labor rates are EBSA estimates.

²³⁹ This is calculated 17,333 × 0.05 × (\$0.05 + \$0.55) = \$520.

²⁴⁰ The burden is estimated as follows: 17,300 claims × 1 percent × 0.5 hours + 17,300 claims × 1 percent × 0.25 hours = 130 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 17,300 claims × 1 percent × 0.5 hours × \$105.01 + 17,300 claims × 1 percent × 0.25 hours × \$55.23 = \$11,472. Labor rates are EBSA estimates.

²⁴¹ The burden is estimated as follows: (13,000 claims × 75 percent × 1 hour) + (13,000 claims ×

75 percent × 0.25 hours) = 16,250 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (13,000 claims × 75 percent × 0.25 hours × \$105.01) + (13,000 claims × 75 percent × 1 hour × \$55.23) = \$1,544,628. Labor rates are EBSA estimates.

²⁴² This is calculated 13,000 × 0.05 × (\$0.05 + \$0.55) = \$390.

TABLE 8—ANNUAL BURDEN AND COST TO SELECT A CERTIFIED IDR ENTITY AND NOTIFY THE DEPARTMENTS OF SELECTION FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
13,000	16,250	\$1,544,628	\$390	\$1,545,018

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Additionally, no later than 10 business days after the date of selection

of the certified IDR entity with respect to a payment determination for a qualified IDR item or service, the provider or facility and the plan or issuer must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service furnished by such provider or facility through the Federal IDR portal. The Departments estimate for providers and issuers, it will take an average of 2.5 hours for a medical and health services manager to write the offer and 30 minutes for a clerical worker to prepare and send the offer. The burden for each plan, issuer, and FEHB carrier would be

3 hours, with an equivalent cost of approximately \$290. As shown in Table 9, for the 17,333 payment determinations that will go through submission of offer, the annual burden would be 103,998 hours, with an annual equivalent cost estimate of \$10.1 million.²⁴³ The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$1,040.²⁴⁴

TABLE 9—ANNUAL BURDEN AND COST TO PREPARE AND SUBMIT OFFER FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
17,333	103,998	\$10,057,993	\$1,040	\$10,059,033

After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier of the payment determination and the reason for such determination, in a form and manner specified by the Departments.²⁴⁵ The cost of preparing and delivering this notice is assumed to be included in the certified IDR entity fee paid by the plan or issuer, or provider or facility, to conduct the review.²⁴⁶

If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the permitted considerations, with respect to the qualified IDR item or service. The cost of preparing and delivering this written

decision is included in the certified IDR entity fee paid by the provider, facility, plan, issuer, or FEHB carrier. When determining the out-of-network rate, the certified IDR entity must consider the QPA and must consider the other statutory factors when a party presents credible information relating to those factors clearly demonstrating the QPA is materially different from the appropriate out-of-network rate, or where the offers are equally distant from the QPA but in opposing directions.

Additionally, the selected certified IDR entity must provide the payment determination and the reasons for such to the Departments. The Departments also assume that the cost of preparing and delivering this written decision is included in the certified IDR entity fee paid by the provider, facility, plan, issuer, or FEHB carrier.

After a final determination, the certified IDR entity must maintain records of all claims and notices

associated with the Federal IDR process for 6 years. The certified IDR entity must store the documents in a manner necessary to meet the requirements of these interim final rules. The certified IDR entities must make such records available for examination by the plan, issuer, FEHB carrier, provider, facility, or state or Federal oversight agency upon request, except where such disclosure would violate state or Federal privacy laws. The Departments assume it will take 30 minutes for a clerical worker to establish the records for each IDR payment determinations. The burden for each certified IDR entity would be 30 minutes, with an equivalent cost of approximately \$28. As shown in Table 10, for the maintenance and recordkeeping of 17,333 claims, the annual burden would be 8,667 hours, with an annual

²⁴³ The burden is estimated as follows: (17,333 claims × 2.5 hours + 17,333 claims × 0.5 hours) + (17,333 claims × 2.5 hours + 17,333 claims × 0.5 hours) = 103,998 hours for providers and issuers. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are

applied in the following calculation: (17,333 claims × 2.5 hours × \$105.01 + 17,333 claims × 0.5 hours × \$55.23) + (17,333 claims × 2.5 hours × \$105.01 + 17,333 claims × 0.5 hours × \$55.23) = \$10,057,993. Labor rates are EBSA estimates.

²⁴⁴ This is calculated (17,333 × 0.05 × (\$0.05 + \$0.55) + (17,333 × 0.05 × (\$0.05 + \$0.55)) = \$1,040.

²⁴⁵ IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

²⁴⁶ Under Section 103 of the No Surprises Act, the party whose offer was not chosen by the certified IDR entity is responsible for paying the IDR entity's fee.

equivalent cost burden estimate of \$0.5 million.²⁴⁷

TABLE 10—ANNUAL BURDEN AND COST FOR THE CERTIFIED IDR ENTITY TO MAINTAIN RECORDS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
17,333	0	\$0	\$478,651	\$478,651

Summary

The total hour burden associated with the Federal IDR process for hospital and emergency department claims is 211,376 hours with an equivalent cost of \$20,666,498. The total cost associated with the Federal IDR process for hospital and emergency claims is \$481,294.

Half of the burden associated with the Federal IDR process for hospital and

emergency departments is estimated to be allocated to health care plans, issuers, and FEHB carriers, and the other half is estimated be allocated to health care providers and facilities. As shown in Tables 11 through 13, HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately, 95,119 hours at an equivalent cost of \$9,299,924 and a cost

burden of \$216,582. DOL and the Department of the Treasury will each account for 25 percent of the burden, or approximately 52,844 hours at an equivalent cost of \$5,166,624 and a cost burden of \$120,324. OPM will account for 5 percent of the burden or approximately 10,569 hours at an equivalent cost of \$1,033,325 and a cost burden of \$24,065.

TABLE 11—HHS SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
49,477	95,119	\$9,299,924	\$1,189	\$215,393	\$9,516,506

TABLE 12—DOL AND DEPARTMENT OF THE TREASURY’S SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
27,487	52,844	\$5,166,624	\$661	\$119,663	\$5,286,948

TABLE 13—OPM’S SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
5,497	10,569	\$1,033,325	\$132	\$23,933	\$1,057,390

3. ICRs Regarding Federal IDR Process for Air Ambulance (26 CFR 54.9817–2T, 29 CFR 2590.717–2, and 45 CFR 149.520)

According to the March 2019 Health Insurance Coverage Bulletin, in 2018, 213.2 million individuals had private health insurance.²⁴⁸ In 2017, HCCI estimated that, on average, there were

33.3 air ambulance uses per 100,000 people,²⁴⁹ and the GAO estimated that approximately 69 percent of air transports resulted in an out-of-network bill.²⁵⁰ The Departments do not have data on what percent of out-of-network bills will proceed to the Federal IDR process; however, given the nature of air ambulance services, the Departments

assume that the percentage will be substantially higher than for hospital or emergency department claims. The Departments assume that 10 percent of out-of-network claims for air transport will end up in the Federal IDR process.

Accordingly, the government estimates there will be 4,899 air

²⁴⁷ The burden is estimated as follows: (17,333 claims × 30 minutes) = 8,667 hours for providers and issuers. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (17,333 claims × 30 minutes × \$55.23) = \$478,651. Labor rates are EBSA estimates.

²⁴⁸ Employee Benefits Security Administration. “Health Insurance Coverage Bulletin.” (March 2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

²⁴⁹ Hargraves, John and Aaron Bloshchick. “Air Ambulances-10-Year Trends in Costs and Use.”

Health Care Cost Institute. (2019). <https://healthcostinstitute.org/emergency-room/air-ambulances-10-year-trends-in-costs-and-use>.

²⁵⁰ Government Accountability Office. “Air Ambulance: Available Data Show Privately-Insured Patients are at Financial Risk.” (2019). <https://www.gao.gov/assets/gao-19-292.pdf>.

ambulance service claims submitted to the Federal IDR process each year.²⁵¹

In these interim final rules, air ambulance services are subject to the same requirements for hospital and emergency services in 26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510 (as applicable), except that the items and services for which the requirements of (b)(1) of that section apply shall be understood to be out-of-network air ambulance services, and “qualified IDR items and services” are understood to be air ambulance services.

The Departments estimate that 4,899 air transport disputes will be handled

by the Federal IDR process each year, but the Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. Accordingly, the Departments estimate that 6,532 transport payment determinations will enter into open negotiation.²⁵² The Departments estimate that it will take an average of 2 hours for a medical and health services manager to write each notice of open negotiation and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. As shown

in Table 14, for the 6,532 payment determinations that will enter into open negotiation, the annual burden would be 14,696 hours, with an annual equivalent cost estimate of \$1.5 million.²⁵³ The open negotiation notice must be sent within 30 business days beginning on the day the provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan, issuer, or FEHB carrier regarding such item or service. The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$196.²⁵⁴

TABLE 14—ANNUAL BURDEN AND COSTS TO PREPARE AND SEND THE NOTICE OF OPEN NEGOTIATION PERIOD FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
6,532	14,696	\$1,461,951	\$196	\$1,462,147

For the estimated 4,899 payment determinations that are submitted to the Federal IDR process, the Departments estimate that it will take 2 hours for a legal professional to write the Notice of IDR Initiation and 15 minutes for a clerical worker to prepare and send the initiating notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of

approximately \$224. As shown in Table 15, for the 4,899 payment determinations that will have selected a certified IDR entity, the annual burden would be 11,022 hours, with an annual equivalent cost estimate of \$1.1 million.²⁵⁵ The initiating party may furnish the Notice of IDR Initiation to the other party electronically if the initiating party has a good faith belief

that the electronic method is readily accessible by the other party and the notice is provided in paper form free of charge upon request. The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$147.²⁵⁶

TABLE 15—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF IDR INITIATION FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
4,899	11,022	\$1,096,463	\$147	\$1,096,610

If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing a Notice of IDR Initiation to the Departments, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically through the

Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties. The Departments assume that 1 percent of payment

determinations will be resolved by an agreement on an out-of-network rate after the Federal IDR process has been initiated. The Departments request comment on this assumption. The Departments estimate that it will take, on average, a medical and health services manager 30 minutes to write each notice of open negotiation and a clerical worker 15 minutes to submit the

²⁵¹ The Departments estimate that of the 213.2 million individuals with employer-sponsored health insurance, there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The Departments assume that 10 percent of the out-of-network bills will end up in IDR. (213,200,000 × 0.000333 × 0.69 × 0.1 = 4,899).

²⁵² This is calculated as 4,899/(1 – 0.25) = 6,532.

²⁵³ The burden is estimated as follows: 6,532 claims × 2 hours + 6,532 claims × 0.25 hours =

14,696 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 6,532 claims × 0.25 hours × \$105.01 + 6,532 claims × 2 hours × \$55.23 = \$1,461,951. Labor rates are EBSA estimates.

²⁵⁴ This is calculated 6,532 × 0.05 × (\$0.05 + \$0.55) = \$196.

²⁵⁵ The burden is estimated as follows: 4,899 claims × 2 hours + 4,899 claims × 0.25 hours =

11,022 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 4,899 claims × 0.25 hours × \$105.01 + 4,899 claims × 2 hours × \$55.23 = \$1,096,463. Labor rates are EBSA estimates.

²⁵⁶ This is calculated 4,899 × 0.05 × (\$0.05 + \$0.55) = \$147.

notice to the Federal IDR portal. The burden for each plan, issuer, and FEHB carrier would be 45 minutes, with an

equivalent cost of approximately \$66. As shown in Table 16, for the 49 payment determinations resolved in this

manner, the annual burden would be 37 hours, with an associated equivalent cost of \$3,249.²⁵⁷

TABLE 16—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF AGREEMENT ON AN OUT-OF-NETWORK RATE STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
49	37	\$3,249	\$0	\$3,249

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services select or fail to select a certified IDR entity, they must notify the Departments of their selection or failure to select a certified IDR entity no later than 1 day after such selection or failure. The Departments estimate that in 75 percent of payment determinations, a certified IDR entity will be selected. The Departments request comment on this assumption.

Additionally, the Departments assume that it will take one hour for a legal professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 1.25 hours, with an equivalent cost of approximately \$119. Due to the tight turnaround, the Departments assume this notice will be sent electronically through the Federal IDR portal. As shown in Table 17, for the

3,674 payment determinations that will have a selected a certified IDR entity, the annual burden would be 4,593 hours, with an annual equivalent cost estimate of \$0.4 million.²⁵⁸ The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$110.²⁵⁹

TABLE 17—ANNUAL BURDEN AND COST TO SELECT CERTIFIED IDR ENTITY AND NOTIFY THE DEPARTMENTS OF SELECTION FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
3,674	4,593	\$436,535	\$110	\$436,646

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range if there are an insufficient number of certified IDR entities) through a random selection method. The range of certified IDR entity fees and the administrative fee paid to the Departments by the plan, issuer, or FEHB carrier and the provider of air ambulance services will be addressed in later guidance by the Departments. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider of air ambulance services, plan, issuer, or FEHB carrier must submit to the certified IDR entity: (1) An offer for a payment amount for the qualified IDR item or service furnished by the provider of air ambulance services, expressed both as a dollar amount and as a percentage of the QPA; and (2) information as requested by the certified IDR entity relating to the offer. With the information requested by the certified IDR entity, the parties must include: (A) The coverage area of the plan, issuer, or FEHB carrier; the relevant geographic region for purposes of the QPA; (B) whether the coverage is fully-insured or fully or partially self-insured), if applicable; and (C) the QPA. The parties

may also submit to the certified IDR entity any information relating to the offer submitted by either party, except that the information may not include information on factors described in paragraph 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). The Departments estimate for providers of air ambulance services, issuers, plans, and FEHB carriers, it will take an average of 2 hours for a medical and health services manager to write the offer and 15 minutes for a clerical worker to prepare and send the offer. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. As shown in Table 18, for the 4,899 claims that will go through submission of offers, the annual burden would be 22,044 hours, with an annual equivalent cost estimate of \$2.2 million.²⁶⁰ The Departments assume

²⁵⁷ The burden is estimated as follows: 4,899 claims × 1 percent × 0.5 hours + 4,899 claims × 1 percent × 0.25 hours = 37 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 4,899 claims × 1 percent × 0.5 hours × \$105.01 + 4,899 claims × 1 percent × 0.25 hours × \$55.23 = \$3,249. Labor rates are EBSA estimates.

²⁵⁸ The burden is estimated as follows: (4,899 claims × 75 percent × 1 hour) + (4,899 claims × 75 percent × 0.25 hours) = 4,593 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims × 75 percent × 0.25 hours × \$105.01) + (4,899 claims × 75 percent × 1 hour × \$55.23) = \$436,535. Labor rates are EBSA estimates.

²⁵⁹ This is calculated 3,674 × 0.05 × (\$0.05 + \$0.55) = \$110.

²⁶⁰ The burden is estimated as follows: (4,899 claims × 2 hours + 4,899 claims × 0.25 hours) + (4,899 claims × 2 hours + 4,899 claims × 0.25 hours) = 22,044 hours for providers and issuers. A labor rate of \$105.01 is used for a medical and health

Continued

that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage.

Thus, the mailing cost is estimated to be \$294.²⁶¹

TABLE 18—ANNUAL BURDEN AND COST TO PREPARE AND SUBMIT OFFER FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
4,899	22,044	\$2,192,926	\$294	\$2,193,220

After the certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination.²⁶² The cost of preparing and delivering this notice is included in the \$25 administrative fee paid by the provider of air ambulance services, plan, issuer, or FEHB carrier to conduct the review.

Certified IDR entities also need to notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination and the written decision explaining such determination. If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information

that the certified IDR entity determined demonstrated that the QPA amount was materially different from the appropriate out-of-network rate, based on the required considerations, with respect to the qualified IDR item or service.

Additionally, the certified IDR entity must provide the payment determination and the reasons for such determination to the Departments. The Departments also assume that the cost of preparing and delivering this written decision is included in the certified IDR entity fee paid by the provider of air ambulance services, plan, issuer, or FEHB carrier.

After a final determination, the certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process for 6 years. The certified IDR entity

must make such records available for examination by the plan, issuer, FEHB carrier, provider of air ambulance services, or state or Federal oversight agency upon request, except where such disclosure would violate state or Federal privacy laws. The Departments assume it will take 30 minutes for a clerical worker to establish the records for each determination under the Federal IDR process necessary to meet the requirements. The cost burden for each certified IDR entity would be 30 minutes, with an equivalent cost of approximately \$28. As shown in Table 19, for the maintenance and recordkeeping of 4,899 claims, the annual burden would be 2,449 hours, with an estimated annual equivalent cost burden of \$0.1 million.²⁶³

TABLE 19—ANNUAL BURDEN AND COST FOR THE CERTIFIED IDR ENTITY TO MAINTAIN RECORDS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
4,899	2,499	\$0	\$135,278	\$135,278

Summary

The total hour burden associated with the Federal IDR process for air ambulance services is 52,392 hours with an equivalent cost of \$5,191,124. The total cost burden associated with the Federal IDR process for air ambulance services is \$136,025. Half of the burden associated with the Federal IDR process for air ambulance services is estimated to be allocated to health plans, issuers, or TPAs, and the other half is estimated to be allocated to health care providers. The burden associated with the Federal

IDR process for air ambulance services is assumed to be shared by the Departments and OPM. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden. As shown in Table 20, the hour burden associated with HHS requirements is estimated to be approximately 23,576 hours at an equivalent cost of \$2,336,006. The total cost burden associated with HHS requirement is estimated to be \$61,211. As shown in Table 21, the hour burden

associated with DOL and the Department of the Treasury requirements is estimated to be approximately 13,089 hours at an equivalent cost of \$1,297,781 each. The total cost burden associated with DOL and the Department of the Treasury requirement is estimated to be \$34,006. As shown in Table 22, the hour burden associated with OPM requirements is estimated to be approximately 2,620 hours at an equivalent cost of \$259,556 each. The total cost burden associated with OPM requirement is estimated to be \$6,801.

services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims × 2 hours × \$105.01 + 4,899 claims × 0.25 hours × \$55.23) + (4,899 claims × 2 hours × \$105.01 + 4,899 claims

× 0.25 hours × \$105.01) = \$2,192,926. Labor rates are EBSA estimates.

²⁶¹ This is calculated (4,899 × 0.05 × (\$0.05 + \$0.55)) + (4,899 × 0.05 × (\$0.05 + \$0.55)) = \$294.

²⁶² IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

²⁶³ The burden is estimated as follows: (4,899 claims × 30 minutes) = 2,449 hours for providers and issuers. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims × 30 minutes × \$55.23) = \$135,278. Labor rates are EBSA estimates.

TABLE 20—HHS SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
16,188	23,576	\$2,336,006	\$336	\$60,875	\$2,397,217

TABLE 21—DOL AND DEPARTMENT OF THE TREASURY’S SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
8,993	13,098	\$1,297,781	\$187	\$33,819	\$1,331,787

TABLE 22—OPM’S SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
450	2,620	\$259,556	\$37	\$6,734	\$266,357

3. ICRs Regarding the Request of Extension of Time Periods for Extenuating Circumstances (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

The Departments do not have data on how often entities will request an extension; however, the Departments are of the view that extenuating circumstances will be rare. The Departments assume that 100 plans,

issuers, FEHB carriers, health care and air ambulance service providers, or facilities will annually request an extension starting in 2022 by completing the “Request for Extension due to Extenuating Circumstances” form and attesting that prompt action will be taken to ensure the payment determination under this section is made as soon as administratively practical. The Departments request comment on how many entities are

likely to make such a request. The Departments estimate that it will take a clerical worker 15 minutes to prepare and send the notice. As shown in Table 23, the annual burden would be 25 hours, with an associated equivalent cost of \$1,381.²⁶⁴ The Departments expect these requests to be submitted through the Federal IDR portal, and therefore have not estimated an associated mailing cost.

TABLE 23—ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
100	25	\$1,381	\$0	\$1,381

Summary

The total hour burden associated with requests for extension is 25 hours with an equivalent cost of \$1,381. Half of the burden is estimated to be allocated to health plans, issuers, or TPAs, and the other half is estimated to be allocated to health care providers. The burden is assumed to be shared by the

Departments and OPM. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden. As shown in Table 24, the hour burden associated with HHS requirements is estimated to be approximately 11 hours at an equivalent cost of \$621. As shown in

Table 25, the hour burden associated with DOL and the Department of the Treasury requirements is estimated to be approximately 6 hours at an equivalent cost of \$345 each. As shown in Table 26, the hour burden associated with OPM requirements is estimated to be approximately 1 hour at an equivalent cost of \$69.

²⁶⁴ The burden is estimated as follows: 100 requests × 0.25 hour = 25 hours. A labor rate of

\$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 100

requests × 0.25 hours × \$55.23 = \$1,381. Labor rates are EBSA estimates.

TABLE 24—HHS’S ANNUAL BURDEN AND COSTS REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
45	11	\$621	\$0	\$621

TABLE 25—DOL AND DEPARTMENT OF THE TREASURY’S ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
25	6	\$345	\$0	\$345

TABLE 26—OPM’S ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
5	1.25	\$69	\$0	\$69

5. ICRs Regarding IDR Entity Certification and IDR Entity Monthly Reporting (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

An IDR entity must be certified under standards and procedures set forth in guidance promulgated by the Departments. The Departments estimate that there will be 50 entities that seek IDR certification.

To be certified as a certified IDR entity, the entity will need to submit an application through the Federal IDR portal, demonstrating that it meets the requirements described in these interim final rules. An IDR entity must provide written documentation to the Departments regarding general company information (such as contact information, TIN, and website), as well as the applicable service area in which

the IDR entity intends to conduct payment determinations under the Federal IDR process. The IDR entity must have (directly or through contracts or other arrangements) sufficient arbitration and claims administration, managed care, billing and coding, medical, legal, and other expertise, and sufficient staffing. The IDR entity must also establish processes to ensure against conflicts of interest, including to attesting that such conflicts do not exist, as defined under these interim final rules. The IDR entity will also need to demonstrate its financial stability and integrity. The corresponding paperwork (including 3 years of financial statements) will be submitted through the Federal IDR portal. Finally, each IDR entity that the Departments certify must enter into an agreement with the Departments. That agreement will

include specified provisions encompassed by these interim final rules, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements for certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

The Departments estimate that on average it will take a medical and health services manager 5.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each IDR entity would be 5.35 hours, with an equivalent cost of approximately \$548. As shown in Table 27, for the 50 IDR entities that will go through certification, this results in a cost burden of \$27,468 in the first year.²⁶⁵

TABLE 27—ONE TIME AND ANNUAL BURDEN AND COSTS TO CERTIFY AND RECERTIFY

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	50	0	\$0	\$27,468	\$27,468
2033	10	0	0	2,343	2,343
2024	10	0	0	2,343	2,343
3 Year Average	23.33	0	0	10,718	10,718

Upon selection of a certified IDR entity, the certified IDR entity must submit the administrative fee to the

Departments on behalf of patient and the provider or facility. The Departments estimate that the time

required to complete the information collection is estimated to average a clerical worker 18 hours annually,

²⁶⁵ The burden is estimated as follows: (50 IDR entities × 5.10 hours) + (50 IDR entities × 0.25 hours) = 268 hours. A labor rate of \$105.01 is used

for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following

calculation: (50 IDR entities × 5.10 hours × \$105.01) + (50 IDR entities × 0.25 hours × \$55.23) = \$27,468.

including the time to review instructions, search existing data

resources, gather required data, and complete and review information

collection. As shown in Table 28, this results in a cost burden of \$49,707.²⁶⁶

TABLE 28—ANNUAL BURDEN AND COSTS TO SUBMIT ADMINISTRATIVE FEE STARTING IN 2022

Estimated number of IDR entities participating	Total annual burden (hours)	Total estimated labor cost	Other cost	Total estimated cost
50	0	\$0	\$49,707	\$49,707

Certified IDR entities are required to be recertified every 5 years. The Departments estimate that on average one-fifth of certified IDR entities will need to be recertified each year. Similar to the initial certification process, the IDR entities must ensure the processes are established and complete the

corresponding paperwork, including the certification agreement, through the Federal IDR portal. The Departments estimate that, on average, it will take a medical and health services manager 2.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each certified IDR entity

would be 2.35 hours, with an equivalent cost of approximately \$224. As shown in Table 30, for the 10 certified IDR entities that will go through recertification, this results in a cost burden of \$2,238 in subsequent years.²⁶⁷ Table 29 summarizes these costs over time.

TABLE 29—ONE TIME AND ANNUAL BURDEN AND COSTS TO CERTIFY AND RECERTIFY

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	50	0	\$0	\$27,468	\$27,468
2023	10	0	0	3,343	2,343
2024	10	0	0	2,343	2,343
3 Year Average	23.33	0	0	10,718	10,718

These interim final rules permit an individual, provider, facility, provider of air ambulance services, or group health plan, health insurance issuer offering group or individual health insurance coverage, or FEHB carrier to petition for a denial of a certification or a revocation of a certification with respect to an IDR entity seeking certification or certified IDR entity for

failure to meet certain requirements set forth in the interim final rules. The Departments do not have data on how often such a petition might occur; however, the Departments assume that such a petition will be a rare occurrence. The Departments assume that there will be 3 petitions each year, and it will take on average a medical and health services manager 2 hours

and a clerical worker 15 minutes to prepare the petition. The burden for each IDR entity seeking certification or certified IDR entity would be 2.25 hours, with an equivalent cost of approximately \$224. As shown in Table 30, for the three petitions, this results in a cost burden of \$560.²⁶⁸

TABLE 30—ANNUAL BURDEN AND COSTS ASSOCIATED WITH THE PETITION FOR DENIAL OR WITHDRAWAL OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
3	0	\$0	\$560	\$560

For each month, certified IDR entities will be required to report information on their activities to the Departments. The required information will include the number of Notices of IDR Initiation submitted to the certified IDR entity under the Federal IDR process during the immediately preceding month; the

number of such Notices of IDR Initiation with respect to which a final determination was made; the size of the provider practices and the size of the facilities submitting Notices of IDR Initiation; the number of times the payment amount determined or agreed to exceeded the QPA, specified by items

and services; and the total amount of certified IDR entity fees paid to the certified IDR entity.

Additionally, for each Notice of IDR Initiation, the certified IDR entity must provide a description of the qualified IDR items and services included with respect to the Notice of IDR Initiation, including the relevant billing and

²⁶⁶ The burden is estimated as follows: (18 hours × \$55.23) = \$994.14 each IDR entity. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 × 18 hours × \$55.23) = \$49,707. Labor rates are EBSA estimates.

²⁶⁷ The burden is estimated as follows: (50 IDR entities × 1/5 × 2.1 hours) + (50 IDR entities × 1/5

× 0.25 hours) = 24 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 IDR entities × 1/5 × 2.1 hours × \$105.01) + (50 IDR entities × 1/5 × 0.25 hours × \$55.23) = \$2,343.

²⁶⁸ The burden is estimated as follows: (3 IDR entities × 2 hours) + (3 IDR entities × 0.25 hours) = 6 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (3 IDR entities × 2 hours × \$105.01) + (3 IDR entities × 0.25 hours × \$55.23) = \$560.

service codes; the relevant geographic region for purposes of the QPA; the amount of the offer submitted by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable); the amount of the selected offer expressed as a dollar amount and a percentage of the QPA; the rationale for the certified IDR entity's decision; the practice specialty or type of each provider or facility (as applicable) involved in furnishing each qualified IDR item or service; the identity for each plan or issuer, and provider or facility, with respect to the determination; and for each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

For each month, certified IDR entities will be required to report information on their activities to the Departments relating to air ambulance services. The certified IDR entities will be required to

provide the number of Notices of IDR Initiation submitted under the Federal IDR process that pertain to air ambulance services during the month submitted to the certified IDR entity; the number of such Notices of IDR Initiation with respect to which a final determination was made; the number of times the payment amount exceeded the QPA; and the total amount of certified IDR entity fees paid to the certified IDR entity during the month that data was collected with regard to air ambulance services.

With respect to each Notice of IDR Initiation involving air ambulance claims, the certified IDR entity must also provide a description of each air ambulance service, the point of pick-up (as defined in 42 CFR 414.605) for which the services were provided, the amount of the offer submitted by the group health plan, health insurance issuer, or FEHB carrier and by the nonparticipating provider of air ambulance services expressed as a dollar amount and a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by such plan, issuer, or FEHB carrier or by the provider or facility; the

amount of the offer so selected expressed as a dollar amount and a percentage of the QPA, including the rationale for the certified IDR entity's decision; the air ambulance vehicle type; the identity of the plan, issuer, FEHB carrier, or provider of air ambulance services with respect to such determination; and the number of business days elapsed between selection of the certified IDR entity and the determination of the payment amount by the certified IDR entity.

For each month, certified IDR entities will be required to report the information on their activity to the Departments. The report will be submitted through the Federal IDR portal. The Departments estimate it will take a medical and health services manager 1 hour, on average, to prepare the reports and a clerical worker 15 minutes to prepare and send the report to the Departments each month. The burden for each certified IDR entity would be 1.25 hours, with an equivalent cost of approximately \$118. For the 600 IDR entities, the annual burden would be 750 hours, with an equivalent cost burden of \$71,291 each year.²⁶⁹

TABLE 31—ANNUAL BURDEN AND COST FOR THE IDR MONTHLY REPORT STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
600	0	0	\$71,291	\$71,291

The certified IDR entities are required, following the discovery of a breach of unsecured IIHI, to notify of the breach the provider, facility, or provider of air ambulance services; the plan or issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible. The Departments estimate that three certified IDR entities will have a breach each year. In addition, the

Departments estimate that it will take a medical and health services manager 1 hour, on average, to handle the initial breach and follow the required protocols, and that it will take a general and operations manager 45 minutes, on average, to ensure the protocol is executed and adapt policies accordingly. The burden for each certified IDR entity would be 1.75 hours, with an equivalent cost of approximately \$197. For the three

certified IDR entities, this results in a cost burden of \$591 each year.²⁷⁰ The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$0.09.²⁷¹ The Departments seek comment addressing the costs that will be associated with these interim final rules.

TABLE 32—ANNUAL BURDEN AND COST FOR BREACH NOTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
3	0	\$0.09	\$591	\$591.09

²⁶⁹ The burden is estimated as follows: (50 IDR entities × 1 hour × 12 reports annually) + (50 IDR entities × 0.25 hours × 12 reports annually) = 750 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (200 IDR

entities × 1 hour × 12 reports × \$105.01) + (200 IDR entities × 0.25 hours × 12 reports × \$55.23) = \$71,291.

²⁷⁰ The burden is estimated as follows: (3 certified IDR entities × 1 hour) + (3 certified IDR entities × 0.75 hour) = 5 hours. A labor rate of \$105.01 is used for a medical and health services manager and a

labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (3 certified IDR entities × 1 hour × \$105.01) + (3 certified IDR entities × 0.75 hour × \$122.55) = \$591.

²⁷¹ This is calculated 3 × 0.05 × (\$0.05 + \$0.55) = \$0.09.

Summary

In the first year, the total cost burden associated with the IDR entity certification process is \$149,616. In subsequent years, the total cost burden associated with the IDR entity certification process is \$124,491. The three-year average cost burden associated with the IDR entity certification is \$132,866. The burden associated with the IDR entity certification is shared by HHS, DOL, the Department of the Treasury, and OPM.

As shown in Tables 33 through 35, it is estimated that 45 percent of the burden will be accounted for by HHS, 25 percent of the burden will be accounted for by DOL and the Department of the Treasury each, and 5 percent will be accounted for by OPM. Therefore, the cost burden associated with HHS requirements is \$67,327 in the first year and \$56,021 in subsequent years. The three-year average cost burden associated with HHS requirements is \$59,790. The cost burden associated with each of the DOL and the

Department of the Treasury requirements is \$37,404 in the first year and \$31,123 in subsequent years. The three-year average cost burden associated with DOL and the Department of the Treasury is \$33,217 each. The cost burden associated with OPM requirements is \$7,481 in the first year and \$6,225 in subsequent years. The three-year average cost burden associated with OPM requirements is \$6,643. The Departments seek comment on the assumptions and calculations made in this ICR.

TABLE 33—HHS SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
305	\$0	\$0	\$59,790	\$59,790

TABLE 34—DOL AND THE DEPARTMENT OF THE TREASURY'S SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
170	0	\$0	\$33,217	\$33,217

TABLE 35—OPM'S SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
34	0	\$0	\$6,643	\$6,643

ICRs Regarding Notice of the Right to Good Faith Estimates for Uninsured (or Self-Pay) Individuals (45 CFR 149.610)

Convening providers and facilities are required under 45 CFR 149.610(b) to inform uninsured (or self-pay) individuals of the availability of good faith estimates of expected charges. The notice regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider or convening facility. Additionally, the notice must be prominently displayed (and easily searchable from a public search engine), on the convening provider's or convening facility's website, in the convening provider's or convening facility's office, and on-site where scheduling or questions about the cost of items and services occur. These ICRs estimate the information collection burdens for three groups of provider types: (1) Providers associated with

health care facilities, (2) individual physician practitioners, and (3) wholly physician-owned private practices. For all three groups of providers, the ICRs apply the same methodology to estimate the burden, consisting of the following steps:

- Drafting notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges.
- Displaying the notices on the provider's website, in the provider's office, and on-site where scheduling or questions about the cost of items or services occur.
- Posting a single page notice in at least two prominent locations.
- Printing and materials costs for posting notices.

Details about the requirements of the steps that apply to all 3 provider groups are described once for providers associated with health care facilities and apply equally to the other two provider groups. Any specific differences in estimating the burden to comply with these requirements are detailed for the

specific provider group below. HHS invites comment on the assumptions and calculations made in these ICRs.

Providers Associated With Health Care Facilities

Unique to providers associated with health care facilities, HHS assumes that such providers will enter into agreements with their associated health care facility to provide notice of the availability of good faith estimates of expected charges to uninsured (or self-pay) individuals on their behalf. HHS estimates that for each health care facility it will take an average of 2 hours for a lawyer to draft an agreement and a medical secretary and administrative assistant 2 hours to provide electronic copies to all associated convening providers to sign. As shown in Table 36, this results in an equivalent cost estimate of approximately \$91,770,384 to be incurred as one-time cost in 2021.²⁷² HHS cannot estimate how

²⁷² The burden is estimated as follows: 245,336 health care facilities × 2 hours = 490,672 hours. A

many providers will incur burden to sign the agreement, but assumes the burden to providers will be minimal;

the use of electronic signature portals may reduce the burden to the convening provider. In future years, this agreement

can be included in the contract between the facilities and providers at no additional cost.

TABLE 36—ESTIMATED ONE-TIME AND HOUR BURDEN FOR PROVIDERS ASSOCIATED WITH FACILITIES TO ENTER INTO AGREEMENTS TO PROVIDE NOTICE OF RIGHT TO A GOOD FAITH ESTIMATE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total burden (hours)	Total estimated cost
2021	245,336	245,336	4	981,344	\$91,770,384

HHS assumes that the associated facility will draft the notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider.

Additionally, the notices must be prominently displayed on the convening provider’s website, and in the convening provider’s office, and on-site where scheduling or questions about the cost of items or services occur. Providers may satisfy this requirement by utilizing the language in the standard notice anticipated to be issued by HHS. HHS estimates that for each health care facility, it will take an average of two hours for a lawyer to read and understand the anticipated notice and

draft any additions in clear and understandable language, a medical secretary and administrative assistant 30 minutes to prepare the document for posting within the facility, and a computer programmer 1 hour to post the information on each providers’ website on behalf of the facility. As shown in Table 37, this results in an equivalent cost of approximately \$102,754,069 to be incurred as a one-time cost in 2021.²⁷³

TABLE 37—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR HEALTH CARE FACILITIES (INCLUDING ON BEHALF OF HEALTH CARE PROVIDERS ASSOCIATED WITH HEALTH CARE FACILITIES) TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total burden (hours)	Printing and materials costs	Total estimated cost
2021	245,336	245,336	2.5	858,676	\$25,752	\$102,754,069

HHS assumes that each health care facility will post a single page document in at least 2 prominent locations so uninsured (or self-pay) individuals are provided reasonable notice of their right to a good faith estimate of expected charges. A prominent location in the health care facility may include patient appointment check-in kiosks, reception front-desks, patient appointment scheduling locations, and where patients pay bills. The notices should be drafted in clear and understandable

language, shorter in length, and printed in legible font size. HHS assumes that each facility will incur a printing cost of \$0.05 per page and materials for a total equivalent cost of \$0.10. Hospitals may have a greater number of posting locations because of building size, therefore, HHS anticipates that hospitals will post four additional notices on average and incur an additional cost of \$0.20 each. This results in a one-time equivalent cost of approximately \$24,534 to all non-hospital health care

facilities and an overall one-time cost of approximately \$25,752 when including hospitals.

HHS estimates that the one-time burden for providers and facilities to enter into agreements and for facilities to develop, prepare, print, and post the notices and update their respective websites will be approximately 1,840,020 total burden hours with an associated equivalent cost of approximately \$194,524,453, as shown in Table 38.

labor rate of \$140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × \$140.96 = \$69,165,125. 245,336 health care facilities × 2 hours = 490,672 hours. A labor rate of \$46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × \$46.07 = \$22,605,259. Therefore, 490,672 hours + 490,672 hours = 981,344 total burden hours and \$69,165,125 + \$22,605,259 = \$91,770,381 total annual respondent time cost.

²⁷³ The burden is estimated as follows: 245,336 health care facilities × 2 hours = 490,672 hours. A labor rate of \$140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × \$140.96 = \$69,165,125. 245,336 health care facilities × 0.5 hours = 122,668 hours. A labor rate of \$46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities × 0.5 hours × \$46.07 = \$5,651,315. 245,336 health care facilities × 1 hours = 245,336 hours. A labor rate

of \$113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 245,336 health care facilities × 1 hour × \$113.77 = \$27,911,877. Therefore, 490,672 hours + 122,668 hours + 245,336 hours = 858,676 total burden hours. Additionally, one-time printing and material costs are estimated using the following calculation: .05 × 2 pages × 245,336 impacted health care facilities = 25,752 total one-time cost for printing and materials. The total respondent time costs are \$69,165,125 + \$5,651,315 + \$27,911,877 + \$25,752 = \$102,754,069.

TABLE 38—TOTAL ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR HEALTH CARE FACILITIES (INCLUDING ON BEHALF OF HEALTH CARE PROVIDERS ASSOCIATED WITH HEALTH CARE FACILITIES) TO PROVIDE NOTICE OF RIGHT TO A GOOD FAITH ESTIMATE ²⁷⁴

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Printing and materials costs	Total estimated cost
2021	245,336	245,336	7.5	1,840,020	\$25,752	\$194,524,453

Individual Physician Practitioners

HHS estimates that 145,887 individual physician practitioners will incur burden and cost to comply with this provision.²⁷⁵ HHS estimates an average of 2 hours and 30 minutes for the individual physician practitioner to read and understand the provided notice and draft any additions in clear and understandable language and (for 80% of individual physician practitioners) a computer programmer

one hour to post the information in the provider’s website. HHS estimates that the one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours. This results in an equivalent cost of approximately \$75,075,712.²⁷⁶

HHS assumes that each individual physician practitioner will incur a printing cost of \$0.05 per page and materials for a total equivalent cost of

\$0.10. This results in an annual one-time equivalent cost of approximately \$14,589 to all individual physician practitioners.

HHS estimates that the annual one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours with an associated equivalent cost of approximately \$75,075,712, as shown in Table 39.

TABLE 39—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INDIVIDUAL PHYSICIAN PRACTITIONERS TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE NOTICE ²⁷⁷

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Printing and material costs	Total estimated cost
2021	145,887 (All Physicians)	145,887	2.5	364,717	\$61,797,674
2021	116,709* (Additional burden for Subset of Physicians with Websites).	* 116,709	1	116,709	13,278,038
Total	3.5	481,426	** 75,075,712

* This is calculated as the sum of \$61,797,674 (cost for all individual physician practitioners to draft notice of right to GFE) + \$13,278,038 (cost for computer programmers to post notice of right to GFE on 80% of practitioners’ websites). Total estimated cost of \$75,075,712 includes burden for all individual physician practitioners to draft the notice of right to GFE plus the additional burden for computer programmers to add the notice to the website for the subset (80 percent) of total physicians that have websites, (80 percent of 145,887 = 116,709).

Wholly-Physician-Owned Private Practices

HHS estimates that 120,525 wholly physician-owned private practices will incur burden and cost to comply with this provision.²⁷⁸ For each practice,

HHS estimates an average of 2 hours and 30 minutes for a general and operations manager to read and understand the provided notice and draft any additions in clear and understandable language and a

computer programmer one hour to post the information in the provider’s website. This results in an equivalent cost of approximately \$50,650,005 to be incurred as a one-time cost in 2021.²⁷⁹

²⁷⁴ Estimated cost includes the sum of Table 28 and 29. It also includes computer programming cost to update health care facility websites with uninsured (or self-pay) individuals’ right to the good faith estimate. Total printing and material costs for all health care facilities of \$24,534 to all non-hospital health care facilities and an overall one-time cost of approximately \$25,752 for hospitals.

²⁷⁵ In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. <https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf>; Professionally Active Physicians. KFF. Published May 20, 2020. <https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22>.

²⁷⁶ The burden is estimated as follows: 145,887 individual physician practitioners × 2.5 hours = 364,717 hours. A labor rate of \$169.40 is used for

a physician. The labor rate is applied to the following calculation: 145,887 individual physician practitioners × 2.5 hours × \$169.40 = \$61,783,085. HHS assumes that 80 percent of individual physician practitioners have a website resulting in 116,709 websites needed to be updated with good faith estimate notices. HHS assumes that the physician will pay a computer programmer to make the website update. The burden is estimated as follows: 116,709 websites needing updates × 1 hour = 116,709 hours. A labor rate of \$113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 116,709 websites needing updates × 1 hour × \$113.77 = \$13,278,038. Therefore, 364,717 hours + 116,709 hours = 481,426 total burden hours. The total annual respondent time cost is \$61,783,085 + \$13,278,038 = \$75,061,124. Total printing and material costs are of \$14,589. Therefore, \$75,061,124 + \$14,589 = \$75,075,712.

²⁷⁷ HHS estimates that 80 percent (116,709) of individual physician practitioners have a website. Therefore, estimated cost includes computer programming cost to update individual physician practitioners’ websites with uninsured (or self-pay)

individuals’ right to good faith estimate. HHS assumes that each individual physician practitioner will incur a printing cost of \$0.05 per page and materials for a total equivalent cost of \$0.10. Total printing and material costs of \$14,589 are included.

²⁷⁸ In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. <https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf>; Professionally Active Physicians. KFF. Published May 20, 2020. <https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22>.

²⁷⁹ The burden is estimated as follows: 125,525 wholly physician-owned private practices × 2.5 hours = 301,312 hours. A labor rate of \$122.55 is used for a general and operations manager. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices

HHS assumes that each the wholly physician-owned private practice will incur a printing cost of \$0.05 per page and materials for a total equivalent cost of \$0.10. This results in a one-time equivalent cost of approximately

\$12,052 to all wholly physician-owned private practices. HHS estimates that the annual one-time burden for wholly physician-owned private practices to develop, prepare, print, and post the notices, and

make website updates will be approximately 421,837 total burden hours with an associated equivalent cost of approximately \$50,650,005, as shown in Table 40.

TABLE 40—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR WHOLLY PHYSICIAN-OWNED PRIVATE PRACTICES TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE NOTICE *

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Material and printing costs	Total estimated cost
2021	120,525	120,525	3.5	421,837	\$12,052	²⁸⁰ \$50,650,005

* Estimated cost includes computer programming cost to update wholly physician-owned private practice website with uninsured (or self-pay) individuals' right to a good faith estimate. HHS assumes that each the wholly physician-owned private practice will incur a printing cost of \$0.05 per page and materials for a total equivalent cost of \$0.10. Total printing and material costs of \$12,052 are included.

Summary

HHS estimates that the one-time burden for health care providers (including providers associated with

health care facilities, individual physician practitioners, and wholly physician-owned private practices) and health care facilities to provide notice of the right to a good faith estimate of

expected charges to uninsured (self-pay) individuals will be approximately 2,743,283 total burden hours with an associated equivalent cost of approximately \$320,250,169.

TABLE 41—ESTIMATED TOTAL ONE-TIME COST RELATED TO NOTICE OF RIGHT TO GOOD FAITH ESTIMATE *

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours) ²⁸¹	Total annual labor burden (hours)	Total printing and material costs	Total estimated cost
2021	511,748	511,748	15.5	2,743,283	\$52,393	\$320,250,169

* Tables 38 through 40 are combined to estimate total amounts. This table presents a cumulative 15.5 hours of burden per response for summary purposes.

7. ICRs Regarding Requirements for Provision of Good Faith Estimate of Expected Charges Upon Request of Uninsured (or Self-Pay) Individuals and for Scheduled Items and Services (45 CFR 149.610)

These interim final rules require a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request (45 CFR 149.610) including those items or services furnished by a co-provider or co-facility in conjunction with the primary items or services. HHS

estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement.²⁸² A total of 511,748 providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices will incur the burden and costs associated with generating a good faith estimate.²⁸³ HHS welcomes comments on this estimate.

HHS estimates that it will take an average of 30 minutes for a business operations specialist to determine a patient's insurance status, orally inform the patient of their right to receive a good faith estimate of expected charges,

and provide an oral good faith estimate, if no additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate for provision of good faith estimates where no additional items and services are needed is of \$88,628,201.²⁸⁴

HHS estimates that it will take an average of 30 minutes for a business operations specialist to generate a good faith estimate of expected charges furnished by a co-provider and co-facility for items and services to the convening provider. Given that 1,749,471 (50 percent) of uninsured (or

²⁸⁰ 2.5 hours × \$122.55 = \$36,925,829. 120,525 wholly physician-owned private practices × 1 hour = 120,525 hours. A labor rate of \$113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices × 1 hour × \$113.77 = \$13,712,123. Therefore, the total burden hours are 301,312 + 120,525 = 421,837 and the total equivalent costs are \$36,925,829 + \$13,712,123 = \$50,637,952. The printing and material costs are \$12,052. Therefore, \$50,637,952 + \$12,052 = \$50,650,005.

²⁸⁰ 301,312 + 120,525 = 421,837 and the total equivalent costs are \$36,925,829 + \$13,712,123 = \$50,637,952. The printing and material costs are \$12,052. Therefore, \$50,637,952 + \$12,052 = \$50,650,005.

²⁸¹ This includes the time for providers associated with health care facilities to enter into agreements

with health care facilities to provide good faith estimates on their behalf.

²⁸² The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. See Squitieri, Lee *et al.* "Resuming Elective Surgery during Covid-19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?." *Plastic and reconstructive surgery. Global open* vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are

performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

²⁸³ These estimates include the total number of health care facilities and health care providers from the preceding ICR Regarding Notice of Right to Good Faith Estimate.

²⁸⁴ The burden is estimated as follows: 1,749,471 uninsured (or self-pay) individuals in need of good faith estimates without items and services × 0.50 hours = 874,736 hours. A labor rate of \$101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 0.50 hours × \$101.32 = \$88,628,201.

self-pay) individuals require additional items and services, same number (1,749,471) of claims will be generated by co-providers or co-facilities. Therefore, the annual equivalent cost estimate for good faith estimates sent to convening providers by co-providers or co-facilities is \$88,628,201.²⁸⁵ HHS assumes that all communication between convening provider and convening facility, and co-provider or co-facility will be done electronically. Thus, the cost to generate a good faith estimate for both cases where additional items and services are needed and where no additional items and services are needed is \$354,512,803.²⁸⁶

HHS estimates that it will take an average of 1 hour for a business operations specialist to determine a patient's insurance status, inform uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges, and provide a good faith estimate, if

additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate is \$177,256,402.²⁸⁷ Thus, a total of \$265,884,603 is estimated for business operations specialists, when adding the cost if no additional items and services are needed (\$88,628,201) to the cost if additional items and services are needed (\$177,256,402).

HHS estimates that approximately 90 percent of uninsured (or self-pay) individuals will receive a good faith estimate of expected charges through the mail that is 2 pages in length.²⁸⁸ The remaining 10 percent of uninsured (or self-pay) individuals will receive the good faith estimate via electronic correspondence; costs are therefore accounted for in the 2 preceding paragraphs. HHS assumes that each convening provider or facility will incur a printing cost of \$0.05 per page and

materials for a total equivalent cost of \$0.10 per good faith estimate. Therefore, the annual equivalent cost estimate for printing good faith estimates is \$314,905 for all health care providers and health care facilities.²⁸⁹

HHS assumes that 5% of uninsured (or self-pay) individuals (*i.e.*, 157,452 uninsured (or self-pay) individuals) will request a mailed copy of their written good faith estimate of expected charges to a preferred location.²⁹⁰ HHS assumes that it will take an average of 15 minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. HHS estimates a postage cost of \$0.55 per mailing. Therefore, the annual equivalent cost estimate is \$1,900,057 to mail the good faith estimate for all health care providers and health care facilities.²⁹¹

TABLE 42—ESTIMATED ANNUAL COST AND HOUR BURDEN PER RESPONSE PER HEALTH CARE PROVIDER AND HEALTH CARE FACILITY TO ACCEPT AND FULFILL REQUESTS FOR MAILED GOOD FAITH ESTIMATES OF EXPECTED CHARGES [Mailing costs only]

Occupation	Burden hours per response	Labor cost per hour	Total mailing cost per response
Medical Secretary and Administrative Assistant	0.25	\$46.07	²⁹² \$3.71
Total per Response	0.25	3.71

TABLE 43—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL HEALTH CARE PROVIDER AND HEALTH CARE FACILITY TO ACCEPT AND FULFILL REQUESTS FOR MAILED GOOD FAITH ESTIMATES OF EXPECTED CHARGES

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total labor costs of reporting	Mailing cost	Total annual cost
511,748	157,452	0.25	39,363	\$1,813,458	\$86,599	²⁹³ \$1,900,057

Summary

HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items

and services and upon requests between 2022–2024 to be \$356,727,765 (inclusive of printing, materials, mailing costs) and total burden hours of 3,538,305, as shown in Table 44.

HHS estimates the annual cost for printing and materials to provide written good faith estimates to uninsured (or self-pay) individuals to be \$314,905. The mailing costs of good faith estimates to uninsured (or self-pay)

²⁸⁵ The burden is estimated as follows: 1,749,471 uninsured individuals in need of good faith estimates with additional items and services × 0.50 hours = 874,736 hours. A labor rate of \$101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 0.50 hours × \$101.32 = \$88,628,201.

²⁸⁶ The burden is estimated as follows: \$88,628,201 + \$177,256,402 + \$88,628,201 = \$354,512,803.

²⁸⁷ The burden is estimated as follows: 1,749,471 claims × 1 hour = 1,749,471 hours. A labor rate of \$101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 1 hour × \$101.32 = \$177,256,402.

²⁸⁸ HHS assumes that the good faith estimate will be printed in 8.5" x 11" letter sized paper.

²⁸⁹ The estimate is calculated as follows: \$0.05 cost per page × 2 pages × 3,149,048 uninsured (or self-pay) individuals who receive a written good faith estimate = \$314,905.

²⁹⁰ An estimated 3,149,048 uninsured (or self-pay) individuals who receive a written good faith estimate × 5% = 157,452 uninsured (or self-pay) individuals who request a mailed good faith estimate of expected charges.

²⁹¹ The burden is estimated as follows: 157,452 good faith estimates × 0.25 hours = 39,363 hours. A labor rate of \$46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 157,452

good faith estimates × 0.25 hours × \$46.07 = \$1,813,458. Therefore, 157,452 mailed good faith estimates × \$0.55 postage cost = \$86,599 in mailing costs + \$1,813,458 in annual respondent time cost = \$1,900,057.

²⁹² The cost per respondent is calculated as: \$1,900,057 in medical secretary and administrative assistant annual respondent time cost to mail good faith estimate and mailing costs (printing costs are already accounted for in preceding section) divided by 511,748 health care providers and health care facilities = \$3.71 cost per respondent.

²⁹³ Therefore, 157,452 mailed good faith estimates × \$0.55 postage cost = \$86,599 in mailing costs + \$1,813,458 in annual respondent time cost = \$1,900,057.

individuals is \$86,599 with an annual total burden hour estimate of 39,363 hours and a total annual respondent

time cost of \$1,813,458. This estimate is included in the total cost of \$356,727,765. HHS invites comment on

the assumptions and calculations made in this ICR.

TABLE 44—ANNUAL BURDEN AND TOTAL COST RELATED TO PROVISION OF GOOD FAITH ESTIMATES FOR UNINSURED (OR-SELF-PAY) INDIVIDUALS (LABOR, PRINTING, AND MAILING)

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total annual respondent time cost	Printing and mailing costs (labor cost included)*	Total estimated cost
3,498,942	3,498,942	2.0	3,538,305	\$354,512,803	\$2,214,961	** \$356,727,765

* This is calculated as following: \$314,905 in printing costs + \$86,599 in mailing costs + \$1,813,458 in estimated annual respondent time cost to mail good faith estimate = \$2,214,961. The Department assumes that it will take an average of fifteen minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. The annual burden hours associated with printing and mailing a good faith estimate of expected charges is 39,363 hours.

** The total estimated cost burden is the sum \$88,628,201 (the GFE costs without co-providers or co-facilities) + \$177,256,402 (the GFE costs with co-providers or co-facilities) + 88, 628, 201 (the GFE costs to convening providers) + \$2,214,961 (printing and mailing costs, including labor).

8. ICRs Regarding Patient-Provider Dispute Resolution Process (45 CFR 149.620)

These interim final rules enable uninsured (or self-pay) individuals to initiate a patient-provider dispute resolution process if their final billed charges are in excess of the expected charges by at least \$400 more than the amount listed in the good faith estimate supplied by the provider or facility. HHS does not have data on how many claims will be likely to result in patient-provider dispute resolution. For the estimates in this section, HHS relied on the experience of New York State. In 2015–2018 New York State had 1,486 disputes involving surprise bills submitted to IDR, 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to enrollment in self-insured plans.²⁹⁴ For purposes of this analysis, HHS assumes that going forward, New York State will continue to see 40 IDR cases each year involving surprise bills for individuals enrolled with self-insured plans. Accordingly, the Departments estimate that there will be 26,659 claims that result in patient-provider dispute resolution each year.²⁹⁵

²⁹⁴ See https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf.

²⁹⁵ The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is \$400 or greater more than the total expected charges listed in the good faith estimate, therefore 3,332,326 × 10% = 333,233. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,233 × 8% = 26,659.

HHS estimates that it will take an average of 2 hours for an uninsured (or self-pay) individual or, if they use an authorized representative, 1 hour for their authorized representative to write, prepare, and send the notice to initiate the patient-provider dispute resolution to the Secretary of HHS. HHS assumes that uninsured (or self-pay) individuals will self-represent in 90% of the cases, while the remaining 10% will be represented by the uninsured (or self-pay) individual's authorized representative, as allowed by these interim final rules.

HHS assumes the authorized representative will be a lawyer. Additionally, HHS assumes that a small percentage of uninsured (or self-pay) individuals or their authorized representatives will be asked to resubmit or send additional materials to complete the initiation process. This results in an annual equivalent cost estimate of \$3,789,694.²⁹⁶ The patient-provider dispute resolution initiation notice must be submitted to the Secretary of HHS within 120 calendar

²⁹⁶ The burden is estimated as follows: 26,659 × 90% = 23,993 uninsured (or self-pay) individuals will self-represent. 23,993 × 2 hours = 47,986 hours. A labor rate of \$64.32 is used for uninsured (or self-pay) individuals (all occupations). The labor rate is applied in the following calculation: 23,993 claims × 2 hours × \$64.32 = \$3,086,427. HHS assumes that uninsured (or self-pay) individual will appoint an authorized representative in 10% of cases. 26,659 × 10% = 2,666 claims represented by an authorized representative. HHS assumes approximately 15% of uninsured (or self-pay) individuals will need to resubmit or submit additional materials to initiate IDR, either themselves or through their authorized representative. Therefore, the burden estimate is calculated as follows: 23,993 claims × 10% = 2,399 resubmitted claims by individual × 2 hours × \$64.32 (labor rate) = \$129,899. 2,666 claims × 5% = 133 resubmitted claims by authorized representative × 1 hour × \$140.96 (labor rate) = \$18,789. The total annual respondent time cost estimates are added as follows: \$3,086,427 + \$375,785 + \$308,647 + \$18,789 = \$3,789,694. The total burden hours are 55,584.

days of receiving billed charges substantially in excess of the good faith estimate. HHS assumes for uninsured (or self-pay) individuals that 8,973 (34%) of initiation notices, including those that need to be resubmitted with additional materials, will be sent electronically and 17,419 (66%) of the initiation notices, including those that need to be resubmitted with additional materials will be mailed with an associated printing and materials and postage costs of \$12,193.^{297 298} To facilitate communication between parties and compliance with this notice requirement, HHS is concurrently issuing a model notice that the parties may use to satisfy the patient-provider dispute resolution initiation notice requirement. HHS will consider timely use of the model notice in accordance with the accompanying instructions to satisfy the notice requirement.

These interim final rules require the SDR entity to attest to the Secretary of HHS whether a conflict of interest exists with the uninsured (or self-pay) individual, provider, or facility. HHS assumes that it will take an average of one hour for a general and operations manager and one hour for a lawyer to

²⁹⁷ HHS assumes that the average initiation notice sent via mail by uninsured (or self-pay) individuals will be three pages in length and printed on 8.5" × 11" sized paper. HHS assumes a \$0.05 cost in printing and materials cost per page and \$0.55 in postage cost. Therefore, \$0.05 cost per page × 3 pages × 17,419 mailed initiation notices (inclusive of notices that needed to be resubmitted) = \$2,613 in printing and material costs. The postage costs are calculated as \$0.55 cost per postage × 17,419 mailed initiation notices = \$9,580 in postage cost. The total printing and materials and postage costs are therefore \$2,613 + \$9,580 = \$12,193.

²⁹⁸ According to data from the National Telecommunications and Information Agency, 34% 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>.

determine whether a conflict of interest exists. HHS assumes all communication will be done electronically. This results in annual equivalent cost estimate of \$7,024,811, as shown in Table 45.²⁹⁹

TABLE 45—ESTIMATED ANNUAL COST AND HOUR BURDEN RELATED TO ATTESTATION OF CONFLICT OF INTEREST WITH A PATIENT-PROVIDER DISPUTE RESOLUTION INITIATION NOTICE

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	2	53,317	\$7,024,811

These interim final rules also require the selected SDR entity to review eligibility and completeness of the initiation notice and notify uninsured (or self-pay) individuals, providers or facilities of the SDR entity's selection to conduct dispute resolution. Providers and facilities are thereafter required to furnish additional information to the SDR entity within 10 business days after receiving notification of SDR entity selection. This information must include: (1) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute; (2) a copy of the bill provided to the uninsured (or self-pay) individual for items or services

under dispute; and (3) documentation providing evidence to demonstrate the difference between the billed charge and the expected charges in the good faith estimate reflects a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS estimates that it will take an average of 1 hour for a general and operations manager to address these requirements and send to the SDR entity. This results in an annual equivalent cost estimate of \$3,267,013.³⁰⁰

These interim final rules require the SDR entity to assess the information

provided by the provider or facility according to the standards described in 45 CFR 149.620(f) and discussed in section VI.B.7 of the preamble. The SDR entity must respond within 30 days after receipt information from the provider or facility to make determinations on charges to the paid by the uninsured (or self-pay) individual. HHS estimates that it will take an average of 2 hours for a general and operations manager and 2 hours for a lawyer to assess the merits of the submitted information and determine a prevailing party. This results in an annual equivalent cost estimate of \$14,049,622.³⁰¹

TABLE 46—ESTIMATED ANNUAL BURDEN TO ASSESS THE SUBMITTED INFORMATION AND DETERMINE A PREVAILING PARTY

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	4	106,634	\$14,049,622

HHS estimates that it will take an average of 30 minutes for an SDR entity's general and operations manager to notify parties of the IDR determination. This results in an annual equivalent cost estimate of \$1,633,506.³⁰²

The SDR entity must also submit the administrative fee to the Secretary of HHS on behalf of uninsured (or self-pay) individuals. This burden includes time

to review instructions, search existing data resources, gather data needed, and complete and review information collection. HHS estimates that the time required to complete and submit this information collection is estimated to average a clerical worker 1.5 hours per month (or 18 hours annually), with a total annual cost of \$2,982.42, as shown in Table 47.³⁰³ HHS estimates the total annual ongoing costs associated with

the implementation and administration of the patient-provider dispute resolution program, including system maintenance, and program support, is estimated to be 12.6 million this cost will be offset by the collection of the \$25 administrative fee, resulting in a total anticipated collection of \$655,475 and a total annual cost to the Federal Government of \$12 million.

²⁹⁹ The burden is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of \$122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 1 hour × \$122.55 = \$3,267,013. The burden for legal review is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of \$140.96 is used for a lawyer. The labor rates are applied in the following calculation: 26,659 claims × 1 hour × \$140.96 = \$3,757,798. The total annual response time cost estimates are added as follows: \$3,267,013 + \$3,757,798 = \$7,024,811. The total burden hours are 53,317.

³⁰⁰ The burden is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of \$101.32 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 1 hour × \$122.55 = \$3,267,013. Total burden hours are 26,659 hours.

³⁰¹ The burden is estimated as follows: 26,659 claims × 2 hours = 53,317 hours. A labor rate of \$122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 2 hours × \$122.55 = \$6,534,026. The burden for legal review is estimated as follows: 26,659 claims × 2 hours = 53,317 hours. A labor rate of \$140.96 is used for a lawyer. The labor rates are applied in the following

calculation: 53,317 × 2 hours × \$140.96 = \$7,515,596. The total annual respond time cost estimates are calculated as follows: \$6,534,026 + \$7,515,596 = \$14,049,622. The total annual burden hours are 106,634 hours.

³⁰² The burden is estimated as follows: 26,659 claims × 0.50 hours = 13,329 hours. A labor rate of \$122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 0.50 hours × \$122.55 = \$1,633,506.

³⁰³ The burden is estimated as follows: A labor rate of \$55.23 is used for a clerical worker. The labor rate is applied in the following calculation: 3 annual responses × 18 hours × \$55.23 = \$2,982.42.

TABLE 47—ESTIMATED ANNUAL BURDEN AND COST RELATED TO SDR SUBMISSION OF THE ADMINISTRATIVE FEE TO HHS

Estimated number of responses	Total annual burden (1.5 hours × 12 months)	Annual cost per IDR entity	Annual cost for all responses
3	18	994.14	\$2,982.42

Summary resolution process for uninsured (or self-pay) individuals and providers and facilities is 255,524 hours with an equivalent cost of \$29,764,646, as shown in Table 48.³⁰⁴ HHS invites comment on the assumptions and calculations made in this ICR.

The total annual burden associated with the patient-provider dispute

TABLE 48—ANNUAL BURDEN AND COST RELATED TO PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS FOR UNINSURED (SELF-PAY) INDIVIDUALS AND PROVIDERS AND FACILITIES

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	13.50	255,524	\$29,764,646

9. ICRs Regarding Patient-Provider Dispute Resolution Entity Certification (45 CR 149.620) 149.620(d). HHS estimates that there will be between 1 and 3 entities that HHS contracts with to be an SDR entity. To be an SDR entity, the entity will need to establish the processes and complete the corresponding paperwork. HHS estimates that on average it will take a general and operations manager 5 hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. As shown in Table 49, this result in an equivalent cost burden of \$1,554 in the first year.³⁰⁵

An SDR entity contracted by HHS must be certified under standards and procedures set forth in 45 CFR

TABLE 49—ESTIMATED FIRST YEAR ONE-TIME COST ANNUAL BURDEN AND COST RELATED TO PATIENT-PROVIDER SDR ENTITY CERTIFICATION PROCESS COST RELATED TO PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
3	3	5.25	15.75	\$1,873

HHS estimates that on average one-third of SDR entities (*i.e.*, one of the three contracted organizations) will need to be recertified or reapproved, through the contracting process, each year and that on average it will take a general and operations manager 2 hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. This results in an equivalent cost burden of \$257.³⁰⁶ The total annual burden associated with the SDR entity certification is 16 hours with an equivalent cost of \$1,873. In subsequent years, the total hour burden associated with the SDR entity certification or recertification is 2.25 hours with an equivalent cost of \$257. HHS will assess whether the SDR entity’s meets the certification standards as discussed in section VI.B.5. of this preamble as part of contracting per the contract period. HHS invites comment on the assumptions and calculations made in this ICR.

³⁰⁴ The total estimated cost burden is the sum of \$3,789,694 (the cost for uninsured or self-pay individuals and authorized representatives to write, prepare and send the initiation notice for the patient-provider dispute resolution to the Secretary of HHS, including resubmission costs) + \$7,024,811 (the cost for SDR entities to attest whether a Conflict of Interest exists with the uninsured or self-pay individual, provider or facility) + \$3,267,013 (the cost for uninsured or self-pay individuals and providers or facilities to furnish additional information to selected SDR entities) + \$14,049,622 (the cost for the SDR entity to carry out the dispute

outcome analysis for uninsured or self-pay individuals and providers and facilities) + 1,633,506 (the cost for the SDR entity to notify the parties of the SDR entity’s determination) = \$29,764,646. These costs represent 13.5 burden hours.

³⁰⁵ The burden is estimated as follows: (3 SDR entities × 5 hours) + (3 SDR entities × 0.25 hours) = 15.75 hours. A labor rate of \$101.32 is used for a general and operations manager and a labor rate of \$46.07 is used for a medical secretary and administrative assistant. The labor rates are applied

in the following calculation: (3 SDR entities × 5 hours × \$101.32) + (3 SDR entities × 0.25 hours × \$46.07) = \$1,554.

³⁰⁶ The burden is estimated as follows: (1 SDR entities × 2 hours) + (1 SDR entities × 0.25 hours) = 2.25 hours. A labor rate of \$122.55 is used for a general and operations manager and a labor rate of \$46.07 is used for medical secretary and administrative assistant. The labor rates are applied in the following calculation: (1 SDR entities × 2 hours × \$122.55) + (1 SDR entities × 0.25 hours × \$46.07) = \$257.

TABLE 50—ANNUAL BURDEN AND COST RELATED TO SDR ENTITY RE-CERTIFICATION PROCESS

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
2023	1	1	2.25	2.25	\$257

10. Summary

The total hour burden in the first six months associated with the Federal IDR process is 3,400,460 hours with an equivalent cost burden of \$366,082,073. The total annual hour burden associated with the Federal IDR process is 4,972,056 hours with an equivalent cost burden of \$518,688,160.

The Departments assume that half of the burden associated with the required notices will be allocated to plans, issuers, and FEHB carriers and the other half of the burden will be allocated to providers, facilities, and providers of air ambulance services. The burden of the plans, issuers, and FEHB carriers will be allocated toward the hour burden of DOL, the Department of the Treasury, and OPM, and the burden of the providers will be allocated toward the hour burden of HHS. The burden of IDR entities will be fully allocated toward the cost burden.

The total annual hour burden in the first six months associated with the Federal IDR process associated with HHS requirements is estimated to be 3,327,917 hours with an equivalent cost burden of \$358,970,847. The total annual hour burden is 4,826,970 hours with an equivalent cost burden of \$504,465,709.

The total annual hour burden in the first six months associated with the Federal IDR process associated with DOL requirements is estimated to be 32,974 hours with an equivalent cost of \$3,232,375. The total annual hour burden is 65,948 hours with an equivalent cost burden of \$6,464,751.

The total annual hour burden in the first six months associated with the Federal IDR process for the Department of the Treasury is estimated to be 32,974 hours with an equivalent cost of \$3,232,375. The total annual hour burden is estimated to be 65,948 hours with an equivalent cost burden of \$6,464,751.

The total annual hour burden in the first six months associated with the Federal IDR process for OPM is estimated to be 6,595 hours with an equivalent cost of \$646,475. The total annual hour burden is estimated to be 13,190 hours with an equivalent cost burden of \$1,292,950.

In terms of the cost burden, the total cost burden in the first six months associated with the Federal IDR process is \$610,675. The first year associated with the Federal IDR process is \$1,206,242. In subsequent years, the total cost burden associated with the Federal IDR process is \$1,143,314. Thus, the 3-year average cost burden is \$1,164,290.

The Departments classify the burden born by IDR entities and certified IDR entities as a cost burden. For certification, re-certification, and monthly reporting requirements, 45 percent of the burden will be allocated toward the cost burden of HHS, while DOL and the Department of the Treasury will each be allocated 25 percent of the burden, and OPM will be allocated 5 percent of the burden. As shown in Table 51, for HHS requirements, the total cost burden associated with the Federal IDR process in the first six months is \$392,214. The

total cost burden in the first year is estimated to be \$784,429 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be \$735,318. Thus, the 3-year average cost burden associated with HHS requirements is \$751,688.

As shown in Table 52, for DOL requirements, the total cost burden associated with the Federal IDR process in the first six months is \$99,300. The total cost burden in the first year is estimated to be \$191,734 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be \$185,452. Thus, the 3-year average cost burden associated with DOL requirements is \$187,546.

As shown in Table 52, for the Department of the Treasury requirements, the total cost burden associated with the Federal IDR process in the first six months is \$99,300. The total cost burden in the first year is estimated to be \$191,734 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be \$185,452. Thus, the 3-year average cost burden associated with the Department of the Treasury requirements is \$187,546.

As shown in Table 53, for OPM requirements, the total cost burden associated with the Federal IDR process in the first six months is \$19,860. The total cost burden in the first year is estimated to be \$38,347 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be \$37,090. Thus, the 3-year average cost burden associated with OPM requirements is \$37,509.

TABLE 51—HHS SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	4,059,610	4,103,368	1.1763434	4,826,970	\$504,465,709	\$784,429
2023	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	735,318
2024	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	735,318
3 Year Average	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	751,688

TABLE 52—DOL'S AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	22,257	36,675	1.7981697	65,948	\$6,464,751	\$191,734

TABLE 52—DOL’S AND DEPARTMENT OF THE TREASURY’S SUMMARY TABLE—Continued

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2023	22,257	36,675	1.7981697	65,948	6,464,751	185,452
2024	22,257	36,675	1.7981697	65,948	6,464,751	185,452
3 Year Average	22,257	36,675	1.7981697	65,948	6,464,751	187,546

TABLE 53—OPM’S SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	22,257	5,986	2.2034535	13,190	\$1,292,950	\$38,347
2023	22,257	5,986	2.2034535	13,190	1,292,950	37,090
2024	22,257	5,986	2.2034535	13,190	1,292,950	37,090
3 Year Average	22,257	5,986	2.2034535	13,190	1,292,950	37,509

These paperwork burden estimates are summarized as follows:

Agency: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 0938–NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 4,059,610.

Estimated Number of Annual Responses: 4,103,368.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 4,826,970 (3,327,917 during the first six months).

Estimated Total Annual Burden Cost: \$751,688 (\$392,214 during the first six months).

Agency: Employee Benefits Security Administration, Department of Labor.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 1210–New.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257.

Estimated Number of Annual Responses: 36,675.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 65,948 (32,974 during the first six months).

Estimated Total Annual Burden Cost: \$187,546 (\$99,300 during the first six months).

Agency: Internal Revenue Service, Department of the Treasury.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 1545–New.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257

Estimated Number of Annual

Responses: 36,675.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 65,948 (32,974 during the first six months).

Estimated Total Annual Burden Cost: \$187,546 (\$99,300 during the first six months).

Agency: Office of Personnel Management.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257.

Estimated Number of Annual

Responses: 5,986.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 13,190 (6,595 during the first six months).

Estimated Total Annual Burden Cost: \$37,509 (\$19,860 during the first six months).

11. ICRs Regarding Internal Claims and Appeals and External Review Requirements for Non- Grandfathered Plans and Grandfathered Plans—Applicability (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, and 45 CFR 147.136)

The No Surprises Act extends the protections related to external reviews to grandfathered plans. Grandfathered plans must comply either with a state external review process or a Federal review process. The disclosure requirements of the Federal external

review process require: (1) A preliminary review by plans of requests for external review; (2) IROs to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans to notify the claimant and IRO if it reverses its decision; (6) the IRO to provide notice of the final external review decision to the claimant and plan; and (7) the IRO to maintain records for six years.

The Departments already have an existing information collection on the claim, appeals, and external review requirements for non-grandfathered plans (1210–0144). Due to these interim final rules, the Departments have added the burden associated with the external review requirements for grandfathered plans and non-grandfathered plans in the information collection. The burden associated with the additional standards that non-grandfathered and grandfathered ERISA-covered plans must meet is shared equally between the Department of Labor and the Department of the Treasury. The burden associated with the additional standards that non-grandfathered and grandfathered non-Federal governmental plans and individual market policies must meet is assigned to the Department of Health and Human Services.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. Prior to the interim final rules, the Departments estimate that there are approximately 8.1 million participants in ERISA-covered plans in

the states which have no external review laws or whose laws do not meet the Federal minimum requirements.³⁰⁷ These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants³⁰⁸ and that there will be approximately 12,275 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external

reviews are actually eligible to proceed to an external review,³⁰⁹ therefore it is expected that there will be about 16,261 (12,275/0.7549) requests for external review. In addition, a 2 percent increase in the number of out-of-networks claims was incorporated in the estimate to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review.

As shown in Table 54, the hour burden related to the preliminary review by grandfathered and non-grandfathered plans subject to ERISA of the request for external review is estimated to be 4,0655 hours (16,261 * 0.25 hours) with an equivalent cost of

\$373,303 (4,065 hours * \$91.83). The Departments assume that plans have a human resources specialist with a labor rate of \$91.83. The human resource specialist will spend an average of 15 minutes for each of the requests, for a plan to make an eligibility determination. Plans will already have conducted internal reviews for eligible claimants; therefore, the required information for plans to make this determination should be readily available. Additionally, plans will incur material costs of \$0.05 for paper and printing and \$0.55 for postage for each request for external review, resulting in a cost of \$9,756 (16,261 * \$0.60).

TABLE 54—ANNUAL BURDEN AND COST FOR PLANS TO CONDUCT A PRELIMINARY REVIEW OF THE REQUEST FOR THE EXTERNAL REVIEW STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	16,261	4,065	\$373,303	\$9,756	\$383,060

Once an eligibility determination is made, plans must provide the IRO with all documentation and other information considered in making an adverse benefit determination. The Departments assume that plans have clerical staff with a labor rate of \$55.23. The clerical staff will spend an average of 5 minutes for each of the requests for

a plan to send documentation to the IRO. As shown in Table 55, for the 12,275 verified requests for external review the hour burden for grandfathered and non-grandfathered plans is estimated as 1,023 hours (12,275 * 5 minutes), with an equivalent cost of \$56,494 (1,023 * \$55.23). Additionally, plans will incur material

costs of \$0.05 for each sheet of paper. The Departments assume that each set of documentation will be 20 pages. Plans will also incur a cost of \$0.55 for postage for each set of documentation, resulting in a cost burden of \$19,026 (12,275 × \$0.05 × 20 + 12,275 * \$0.55). The Departments estimate that this will cost, on average, \$1.55 per claimant.

TABLE 55—ANNUAL BURDEN AND COST FOR PLANS TO PROVIDE THE IRO WITH DOCUMENTATION STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	1,023	\$56,494	\$19,026	\$75,519

IROs must also send each eligible claimant a notice of eligibility and acceptance. The Departments assume that the IRO has clerical staff with a labor rate of \$55.23 that will spend, on average 5 minutes per claimant preparing the notice, and that IROs incur an average cost of \$0.60 to print and mail the notice. As shown in Table

56, for the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice of eligibility and acceptance is estimated to be \$56,493 (12,275 × 5 minutes × \$55.23). Additionally, IROs will incur material costs of \$0.05 for each sheet of paper. The Departments assume that each notice of eligibility and acceptance

will be 1 page. Plans will also incur a cost of \$0.55 for postage for each set of documentation, resulting in a cost of \$7,365 (12,275 × \$0.05 + 12,275 * \$0.55). Thus, the total cost burden relating to the notice of eligibility and acceptance is \$63,858.

³⁰⁷ These states are Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.

https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.

³⁰⁸ AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008.

³⁰⁹ North Carolina Department of Insurance. "Health Insurance Smart NC: Annual Report on External Review Activity 2013." <https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531>.

TABLE 56—ANNUAL BURDEN AND COST FOR IROS TO SEND NOTICES OF ELIGIBILITY AND ACCEPTANCE STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	\$0	\$63,858	\$63,858

IROs are required to send to plans all documents that claimants submit. The Departments do not know what fraction of claimants will submit additional documentation, but for purposes of this burden analysis assume that half of claimants (6,137) do. The Departments assume that the IRO has clerical staff with a labor rate of \$55.23 that will spend, on average 5 minutes per claimant preparing and forwarding the required documents, and that IROs incur an average cost of \$1.05 to print and mail the documents. As shown in Table 57, for the 6,137 verified requests for external review, the cost burden for the clerical worker to send the claimants' documentation to the plans is estimated to be \$28,247 (6,137 × 5 minutes × \$55.23). Additionally, IROs will incur material costs of \$0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of \$0.55 for postage for each set of documentation, resulting in a cost of \$6,444 (6,137 × \$0.05 × 10 + 12,275 × \$0.55). Thus, the total cost burden relating to preparing and forwarding the required documents is \$34,691.

TABLE 57—ANNUAL BURDEN AND COST FOR IROS TO SEND PLANS ALL DOCUMENTS THAT CLAIMANTS SUBMIT STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	6,137	0	\$0	\$34,691	\$34,691

IROs are required to provide the notice of the final external review decision to the claimant and plan. The Departments estimate that preparing and sending the notices for each of the 12,275 external reviews will take IRO clerical staff, with a labor rate of \$55.23, on average 5 minutes per claimant, and that IROs will incur an average cost of \$1.05 to mail the documents. As shown in Table 58, for the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice is estimated to be \$56,494 (12,275 × 5 minutes × \$55.23). Additionally, IROs will incur material costs of \$0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of \$0.55 for postage for each set of documentation, resulting in a cost of \$12,888 (12,275 × \$0.05 × 10 + 12,275 × \$0.55). Thus, the total cost burden relating to notifying the claimant and plan of the final external review decision is \$69,382.

TABLE 58—ANNUAL BURDEN AND COST FOR IROS TO NOTIFY THE CLAIMANT AND PLAN OF THE RESULT OF THE FINAL EXTERNAL REVIEW DECISION STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	\$0	\$69,382	\$69,382

IROs also are required to maintain records of all claims and notices associated with the external review process for six years. The Departments are of the view that these documents would be retained as a customary part of business, but estimate that clerical staff will spend on average an additional 5 minutes per claimant ensuring all files are complete. As shown in Table 59, for the 12,275 verified requests for external review, the cost burden for the clerical worker to maintain records is estimated to be \$56,494 (12,275 × 5 minutes × \$55.23).

TABLE 59—ANNUAL BURDEN AND COST FOR IROS TO MAINTAIN RECORD OF ALL CLAIMS AND NOTICES STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	\$0	\$56,494	\$56,494

The Departments estimate that the Federal external review process will result in an hour burden of 5,088 hours with an equivalent cost of \$429,797 related to external reviews. The cost burden of approximately \$253,207 annually. The cost burden results from the cost associated with preparing and

mailing required notices and documents.

The Departments are not able to estimate the number of reversals and the associated notices to claimants and IROs that plans would send due to reversing prior decisions, but the Departments are of the view that the number would be small.

The existing information collection had an estimated hour burden of 1,394

hours with an equivalent cost of \$97,616 and an estimated cost burden by \$3,002,150.

In summary, the total burden associated the information collection for DOL and the Department of the Treasury, including the existing collection, is approximately 6,482 hours at an equivalent cost of \$527,413 annually. The cost burden is approximately \$3,255,357 annually.

Because the burden is shared equally between the DOL and the Department of the Treasury, the DOL's share is 3,241 hours at an equivalent cost of \$263,706 annually. The DOL's share of the cost burden is \$1,627,679 annually. The summary of burden for DOL and the Department of the Treasury's information collection has also been provided below.

TABLE 60—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	381,826	3,241	\$263,706	\$1,627,679	\$1,891,385
2023	381,826	3,241	263,706	1,627,679	1,891,385
2024	381,826	3,241	263,706	1,627,679	1,891,385
3 Year Average	381,826	3,241	263,706	1,627,679	1,891,385

HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-Federal governmental plans enrollees.³¹⁰ These estimates lead to a total of 32.8 million total enrollees in individual market and non-Federal Government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a two percent increase in the number of out-of-networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review resulting in an adjusted total of 30.7 million for non-grandfathered plans and an adjusted total of 33.3 million for all

individual market and non-Federal Government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-Federal Government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans.

HHS estimated the burden for the disclosure requirements of the Federal external review process to align with the methodologies used to calculate the amounts in Tables 54 through 59. As shown in Table 61, HHS estimates that the disclosure requirements will require 3,066 burden hours that result in \$222,224 in estimated labor costs and \$19,625 in other costs for printing and mailing. The total estimated updated burden for Federal external review to individual market and non-Federal Government plans is \$241,850. This amount includes \$222,729 in costs for non-grandfathered plans and \$19,121 for grandfathered plans. The existing collection for HHS for Federal external review is \$128,876.

TABLE 61—HHS' SUMMARY TABLE NEW COLLECTION BURDEN FOR FEDERAL EXTERNAL REVIEW

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	5,783	3,066	\$222,224	\$19,625	\$241,850
2023	5,783	3,066	222,224	19,625	241,850
2024	5,783	3,066	222,224	19,625	241,850
3 Year Average	5,783	3,066	222,224	19,625	241,850

Summary of Burden

Type of Review: Revised Collection.
Agency: DOL—EBSA.
Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.
OMB Numbers: 1210—0144.
Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 2,524,241.
Estimated Number of Annual Responses: 381,826.
Frequency of Response: Occasionally.
Estimated Total Annual Burden Hours: 3,241.
Estimated Total Annual Burden Cost: \$1,627,679.
Type of Review: Revised Collection.

Agency: Treasury—IRS.
Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.
OMB Numbers: 1545—2182.
Affected Public: Businesses or other for-profits, Not-for-profit institutions.
Estimated Number of Respondents: 2,524,241.

³¹⁰ Individual market data is based on data from MLR annual report for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/>

Data-Resources/mlr. Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost

Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

Estimated Number of Annual Responses: 381,826.
Frequency of Response: Occasionally.
Estimated Total Annual Burden Hours: 3,241.

Estimated Total Annual Burden Cost: \$1,627,679.

Type of Review: Revised Collection.
Agency: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.

OMB Numbers: 0938–1099.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 5,783.

Estimated Number of Annual Responses: 5,783.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 3,066.

Estimated Total Annual Burden Cost: \$241,850.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes

certain requirements with respect to Federal rules that are (1) required to be published as a notice of proposed rulemaking subject to the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b)) and (2) likely to 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.” The Departments use 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.

These interim final rules are exempt from the RFA because the Departments were not required to publish a notice of proposed rulemaking. Therefore, the RFA does not apply and the Departments are not required to either certify that the interim final rules will

not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis. Nevertheless, the Departments carefully considered the likely impact of the interim final rules on small entities in connection with its assessment of the interim final rules’ cost and benefits under Executive Order 12866.

Table 58 summarizes the estimated costs on small issuers, physicians, and providers of air ambulance services. The original analysis was based on a cost per IDR payment determination basis. To break down the cost to a per-entity basis, the Departments assume that the distribution of per-entity costs is proportional to annual receipts. The affected entities are estimated based on the SBA’s size standards. The size standards applied for issuers is North American Industry Classification System (NAICS) 524114, for which a business with less than \$41.5 million in receipts is considered to be small. The size standard applied for physicians is NAICS 62111, for which a business with less than \$12.0 million in receipts is considered to be small.³¹¹

TABLE 62—SUMMARY OF ESTIMATES COSTS ON SMALL ENTITIES

Affected entity	Affected small entities ³¹²	Aggregate annual cost for small entities ³¹³	Annual cost per entity ³¹⁴
Issuer	132	\$714,065	\$5,410
Physicians ³¹⁵	61,890	136,976,819	2,213

The Departments do not have the same level of data used in the table above the air ambulance sub-sector and are of the view that this sub-sector is likely to differ from the ambulance services industry as a whole. In 2020, the total revenue of providers of air ambulance services is estimated to be \$4.2 billion with 1,073 businesses in the industry.³¹⁶ This results in an industry average of \$3.9 million per business. Accordingly, the Departments are of the

view that most providers of air ambulance services are likely to be small entities.

Additionally, this analysis also excludes certified IDR entities and their respective costs, as the Departments do not have information on how many certified IDR entities are likely to be small entities.

Consistent with the policy of the RFA, the Departments seek comment

regarding the impact of these interim final rules on small entities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed agency rule, or a finalization of such a proposal, that may result in an expenditure of \$100 million or more (adjusted annually

³¹¹ U.S. Small Business Administration. “Table of Size Standards.” (August 2019). <https://www.sba.gov/document/support-table-size-standards>.

³¹² For issuers, it is assumed that the size distribution across establishments is the same for issuers as their respective industry. For physicians, it is assumed that the size distribution across employment is the same for physicians as the respective industry. For more information, refer to the Affected Entities section in the Regulatory Impact Analysis.

³¹³ To estimate the proportion of the total costs that would fall onto small entities, the Departments assume that the proportion of costs is proportional to the industry receipts. The Departments are of the view that this assumption is reasonable, as the

number of IDR payment determinations an entity is involved in is likely to be proportional to the amount of business in which the entity is involved. Applying data from the Census bureau of receipts by size for each industry, the Departments estimate that small issuers will incur 0.2 percent of the total costs incurred by all issuers, that physicians in small offices will incur 36.8 percent of total costs incurred by all physicians, and small providers of air ambulance services will incur 31.0 percent of total costs incurred by all providers of air ambulance services. (See Census Bureau. “2017 SUBS Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.” (May 2021). <https://www.census.gov/data/tables/2017/econ/subs/2017-susb-annual.html>.)

³¹⁴ The Annual Cost per Entity is calculated by dividing the estimated Aggregate Annual Cost for

Small Entities by the Estimated Affected Small Entities.

³¹⁵ The costs for physicians refers to the cost associated with each physician. The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis and will be affected by these interim final rules, but the Departments do not have data on how many of the affected physicians are employed in small offices. This analysis is based on the number physicians affected, not the number of physician offices.

³¹⁶ IBIS World. “Air Ambulance Service Industry in the US—Market Research Report.” (December 2020). <https://www.ibisworld.com/united-states/market-research-reports/air-ambulance-services-industry/>.

for inflation with the base year 1995) in any one year by state, local, and tribal governments, in the aggregate, or by the private sector.³¹⁷ However, Section 202 of UMRA does not apply to interim final rules or non-notice rules issued under the ‘good cause’ exemption in 5 U.S.C. 553(b)(B).³¹⁸ For purposes of the UMRA, this rule does not include any Federal mandate that the Departments expect to result in such expenditures by state, local, or tribal governments.

F. Federalism Statement

Executive Order 13132 outlines fundamental principles of Federalism and requires Federal agencies to adhere to specific criteria when 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 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 final rule.

In the Departments’ view, these interim final rules have Federalism implications because they have direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among various levels of government. State and local government health plans may be subject to the Federal IDR process, where a specified state law does not apply. Additionally, the No Surprises Act authorizes states to enforce the new requirements, 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 otherwise not enforcing, or HHS has made a determination that a state has failed to substantially enforce the requirements. However, in the Departments’ view, the Federalism implications of these interim final rules are substantially mitigated because the Departments expect that some states will have their own process for determining the total amount payable

under such a plan or coverage for emergency services and to out-of-network providers at in-network facilities. Where a state has such a specified state law, the state law, rather than the Federal IDR process, will apply. The Departments anticipate that some states with their own IDR process may want to change their laws or adopt new laws in response to these interim final rules. The Departments anticipate that these states will incur a small incremental cost when making changes to their laws.

In general, ERISA section 514 supersedes state laws to the extent that they relate to any covered employee benefit plan, including covered group health plans, and preserves state laws that regulate insurance, banking, or securities. While ERISA prohibits states from regulating a plan as an insurance or investment company or bank, the preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that requirements of Part 7 of ERISA and title XXVII of the PHS Act (including those of the Affordable Care Act) 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 health insurance 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 HIPAA indicates that this is intended to be the “narrowest” preemption of state laws.³¹⁹ Additionally, the No Surprises Act requires that when a state law determines the total amount payable under such a plan, coverage, or issuer for emergency services or to out-of-network providers at in-network facilities, such state law will apply, rather than the Federal IDR process specified in these regulations.

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 as detailed in the July 2021 interim final rule.

While developing these interim final rules, the Departments and OPM 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 and OPM complied with the requirements of Executive Order 13132. The Departments welcome input from affected states regarding this assessment.

G. Congressional Review Act

These interim final rules are determined to be major and 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.

Laurie Bodenheimer,

Associate Director Healthcare and Insurance Office of Personnel Management

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Lily L. Batchelder,

Assistant Secretary of the Treasury (Tax Policy).

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Office of Personnel Management

5 CFR Chapter I

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

³¹⁷ 2 U.S.C. 1501 *et seq.* (1995).

³¹⁸ See OMB, Memorandum for the Heads of Executive Departments and Agencies, M–95–09, “Guidance for Implementing Title II of S.1,” 1995, available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/1995-1998/m95-09.pdf>.

³¹⁹ See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

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. Amend § 890.114 by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 890.114 Surprise billing.

(a) A carrier must comply with requirements described in 26 CFR 54.9816–3T through 54.9816–8T, 54.9817–1T, 54.9817–2T and 54.9822–1T; 29 CFR 2590.716–3 through 2590.716–8, 2590.717–1, 2590.717–2 and 2590.722; and 45 CFR 149.30, 149.110 through 149.140, 149.310, 149.510, and 149.520, 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.

* * * * *

(d)(1) In addition to notification to the Department per 26 CFR 54.9816–8T(b)(2)(iii), 29 CFR 2590.716–8(b)(2)(iii), and 45 CFR 149.510(b)(2)(iii), a carrier must notify the Director of its intent to initiate the Federal IDR process, or its receipt of written notice that a provider, facility, or provider of air ambulance services has initiated the Federal IDR process, upon sending or receiving such notice.

(2) The Director will coordinate with the Departments in resolving matters under 26 CFR 54.9816–8T(c)(4)(vi)(A)(1), 29 CFR 2590.716–8(c)(4)(vi)(A)(1), or 45 CFR 149.510(c)(4)(vi)(A)(1) where fraud or misrepresentation are presented, and matters involving 26 CFR 54.9816–8T(c)(4)(vii)(A)(2), 29 CFR 2590.716–8(c)(4)(vii)(A)(2), and 45 CFR 149.510(c)(4)(vii)(A)(2). The Director will coordinate with the Departments in oversight of reports submitted by certified IDR entities with respect to carriers pursuant to 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), or 45 CFR 149.510(f).

Department of the Treasury Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 3. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ 4. Section 54.9815–2719T is added to read as follows:

§ 54.9815–2719T Internal claims and appeals and external review processes (temporary).

(a) *Scope and definitions*—(1) *Scope*—(i) *In general*. This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010, as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage*. The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 54.9815–1251. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under sections 9816

and 9817 and §§ 54.9816–4T through 54.9816–5T and 54.9817–1T.

(2) *Definitions*. For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination*. An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 54.9815–2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal)*. An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant*. *Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant’s authorized representative.

(iv) *External review*. *External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination*. A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision*. A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO)*. An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act*. The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general*. A group health plan and a health insurance issuer offering group health insurance

coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 54.9815–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan’s benefit determination (whether adverse or not) as soon as possible, taking into

account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan’s benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are

adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(3) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan’s or issuer’s standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(4) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(5) The plan and issuer must disclose the availability of, and contact

information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (1) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(2) of this section.

Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(2) Notwithstanding paragraph (b)(2)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(1) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the

claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503-1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review—(1) In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (ii) of this

section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under sections 9816 and 9817 and §§ 54.9816-1T through 54.9816-6T and 54.9817-1T.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed \$25; it must be refunded to the claimant if the adverse benefit determination (or final

internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing fees for any claimant within a single plan year must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the

determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes.* (i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2), if it meets the temporary standards established by the

Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope.*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812–1, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in sections 9816 and 9817 and §§ 54.9816–4T through 54.9816–5T and 54.9817–1T; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(2) *Conclusion.* In this Example 1, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

(B) *Example 2—(1) Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(2) *Conclusion.* In this Example 2, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment.

Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(C) *Example 3—(1) Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 54.9816–4T do not apply because the treatment did not involve “emergency services” within the meaning of § 54.9816–4T(c)(2)(i). *C* receives an adverse benefit determination, and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(2) *Conclusion.* In this Example 3, the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 54.9816–4T. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(D) *Example 4—(1) Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 54.9816–5T. As a result, *D* receives an adverse benefit determination for the

services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 54.9816–5T.

(2) *Conclusion.* In this *Example 4*, whether the plan was required to decide the claim in a manner consistent with the requirements of § 54.9816–5T involves considering whether the plan complied with § 54.9816–5T, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(E) *Example 5—(1) Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 54.9816–4T(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 54.9816–4T.

(2) *Conclusion.* In this *Example 5*, whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 54.9816–4T(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(F) *Example 6—(1) Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 54.9816–5T(a)

and the fact that those protections may not be waived for neonatology services under § 54.9816–5T(b).

(2) *Conclusion.* In this *Example 6*, medical judgment is necessary to determine whether the correct code was used and compliance with § 54.9816–5T(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

(G) *Example 7—(1) Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 54.9816–5T(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 54.9816–5T(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 54.9816–5T(a) and (b).

(2) *Conclusion.* In this *Example 7*, consideration of whether the plan complied with the requirements in § 54.9816–5T(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed

within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review—(A) In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(1) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(2) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (e.g., worker classification or similar determination);

(3) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(4) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general*. The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(1) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(2) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(3) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(4) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts*. A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(1) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(2) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(3) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(4) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(5) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b) of this section. In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(i) The claimant's medical records;

(ii) The attending health care professional's recommendation;

(iii) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(iv) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(v) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal Government, national or professional medical societies, boards, and associations;

(vi) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(vii) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of

such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(6) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(7) The assigned IRO's written notice of the final external review decision must contain the following:

(i) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(ii) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(iii) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(iv) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(v) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(vi) A statement that judicial review may be available to the claimant; and

(vii) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(viii) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request,

except where such disclosure would violate State or Federal privacy laws.

(iv) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard

review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and

appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years beginning on or after January 1, 2022.

■ 5. Section 54.9816–1T is revised to read as follows:

§ 54.9816–1T Basis and scope (temporary).

(a) *Basis.* This section and §§ 54.9816–2T through 54.9816–8T, 54.9817–1T, 54.9817–2T, 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. This part also establishes an independent dispute resolution process and standards for certifying independent dispute resolution entities.

■ 6. Section 54.9816–2T is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 54.9816–2T Applicability (temporary).

(a) *In general.* (1) 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 § 54.9815–1251), except as specified in paragraph (b) of this section.

(2) The requirements in §§ 54.9816–8T and 54.9817–2T apply to certified IDR entities and group health plans (including grandfathered health plans as defined in § 54.9815–1251) except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 54.9816–4T through 54.9816–8T, 54.9817–1T, 54.9817–2T, and 54.9822–1T do not apply to the following:

* * * * *

■ 7. Section 54.9816–8T is added to read as follows:

§ 54.9816–8T Independent dispute resolution process (temporary).

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable); and a group health plan complete a requisite open negotiation period, and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 54.9816–3T apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under

paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(1) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(2) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(3) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this section, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(1) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(2) The unauthorized person who used the IIHI or to whom the disclosure was made;

(3) Whether the IIHI was actually acquired or viewed; and

(4) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor.

(iv) *Conflict of interest* means, with respect to a party to a payment determination or certified IDR entity, a material relationship, status, or condition of the party or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination.

For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or

future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity, or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of § 54.9816-4T, 29 CFR 2590.716-4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of § 54.9816-5T, 29

CFR 2590.716-5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of § 54.9817-1T, 29 CFR 2590.717-1, or 45 CFR 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 54.9816-3T;

(B) With respect to which a provider or facility (as applicable) or group health plan submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIIH* means IIIH that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1)

Determination of payment amount through open negotiation—(i) *In general*. With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content*. The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service

code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner*. The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied:

(1) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(2) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general*.

With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities*. A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content*. The notice of IDR initiation must include:

(1) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in § 54.9816-4T(c)(2)(i), 29 CFR

2590.716–4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in § 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or 45 CFR 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(2) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(3) State where the qualified IDR item or service was furnished;

(4) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(5) Preferred certified IDR entity;

(6) An attestation that the items and services under dispute are qualified IDR items or services;

(7) Qualifying payment amount;

(8) Information about the qualifying payment amount as described in § 54.9816–6T(d); and

(9) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner*. The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(1) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(2) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary*. The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general*. The plan or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be

treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan and the provider, facility, or provider of air ambulance services, must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity*. The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection*. Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the

non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content*. If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(1) Name of the certified IDR entity;

(2) The certified IDR entity number;

and

(3) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity*. If the plan and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of Health and Human Services and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to

charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) of this section as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must

include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan

makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations set forth in paragraph (c)(3)(i) of this section and the certified IDR entity fee for single determinations as set forth in paragraph (e)(2)(vii) of this section.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(1) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(2) Information requested by the certified IDR entity relating to the offer.

(3) The following additional information, as applicable—

(i) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(ii) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(iii) For plans, information on the coverage area of the plan, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured; and

(iv) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one

of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(1) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(2) The market share held by the provider or facility or that of the plan in the geographic region in which the qualified IDR item or service was provided.

(3) The acuity of the participant, or beneficiary, receiving the qualified IDR

item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(4) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(5) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the plan. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the plan.

(2) *Conclusion.* In this *Example 1*, the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the plan. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2—(1) Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be

delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The plan submits the qualifying payment amount as its offer with no additional information.

(2) *Conclusion.* In this *Example 2*, the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3—(1) Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The plan submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(2) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the plan's offer.

(D) *Example 4—(1) Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The plan submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The plan submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(2) *Conclusion.* In this *Example 4*, both the nonparticipating provider and plan submitted information that is credible and that may be considered by the certified IDR entity. However, only the plan provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the plan has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the plan's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraphs (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination—(A) Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(1) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(2) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial

notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, provider, facility, provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process—(1) Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified

IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1), pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor, as set forth in this paragraph (e) and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations, as well as the requirements regarding certification and revocation (such as specifications for wind-down activities

and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any conflicts of interest arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(1) The certified IDR entity's required duties described in this section; and

(2) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (1) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(2) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(3) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier;

(4) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan; the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(1) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is

an employee, officer, or other agent of the certified IDR entity;

(2) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(3) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(i) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(ii) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(iii) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(iv) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(v) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(4) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the

upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(vii)(A) and (B) of this section as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(1) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(2) A description of the circumstances that require the alternative fee; and

(3) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be

eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) *Conflict-of-interest standards.* In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation—*
(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

- (A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;
- (B) The reason(s) for the petition;
- (C) Whether the petition seeks denial or revocation of a certification;
- (D) Documentation to support the reasons outlined in the petition; and
- (E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) *Effect on certification under petition.* Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a

revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification—(i) Denial of IDR entity certification.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

- (A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);
- (B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor;
- (C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor as part of the certification process;
- (D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or
- (E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

- (A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);
- (B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;
- (C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);
- (D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to

the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan, and provider or facility, with respect to the

notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

■ 8. Section 54.9817–2T is added to read as follows:

§ 54.9817–2T Independent dispute resolution process for air ambulance services (temporary).

(a) *Definitions.* Unless otherwise stated, the definitions in § 54.9816–3T apply.

(b) *Determination of out-of-network rates to be paid by group health plans; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans for out-of-network air ambulance services, plans must comply with the requirements of § 54.9816–8T, except that references in § 54.9816–8T to the additional circumstances in § 54.9816–8T(c)(4)(iii)(C) shall be understood to refer to § 54.9817–2T(b)(2).

(2) *Additional information.*

Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 54.9816–8T(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 54.9816–8T(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 54.9816–8T(b)(2) (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 54.9816–8T(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 54.9816–8T(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 54.9816–8T(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

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 continues 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; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

Subpart C—Other Requirements

■ 10. Section 2590.715–2719 is amended by:

■ a. Revising paragraphs (a)(1), (c)(2)(i), and (d)(1)(i)(A) and (B);

■ b. Adding paragraph (d)(1)(i)(C);

■ c. Adding Examples 3 through 7 to paragraph (d)(1)(ii); and

■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 2590.715–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1)

Scope—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 2590.715–1251. However, the

external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1.

* * * * *

(c) * * *

(2) * * *

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of ERISA section 712 and § 2590.712, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the

requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) * * *

Example 3. (i) *Facts*. A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 2590.716–4 do not apply because the treatment did not involve “emergency services” within the meaning of § 2590.716–4(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion*. In this *Example 3*, the plan’s determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 2590.716–4. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

Example 4. (i) *Facts*. A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 2590.716–5. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 2590.716–5.

(ii) *Conclusion*. In this *Example 4*, whether the plan was required to decide

the claim in a manner consistent with the requirements of § 2590.716–5 involves considering whether the plan complied with § 2590.716–5, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts*. A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 2590.716–4(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 2590.716–4.

(ii) *Conclusion*. In this *Example 5*, whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 2590.716–4(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts*. Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 2590.716–5(a) and the fact that those protections may not be waived for neonatology services under § 2590.716–5(b).

(ii) *Conclusion*. In this *Example 6*, medical judgment is necessary to determine whether the correct code was used and compliance with § 2590.716–5(a) and (b) must also be considered.

Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts*. A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 2590.716–5(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 2590.716–5(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 2590.716–5(a) and (b).

(ii) *Conclusion*. In this *Example 7*, consideration of whether the plan complied with the requirements in § 2590.716–5(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

(g) *Applicability date*. The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years beginning on or after January 1, 2022.

■ 11. Section 2590.716–1 is amended by revising paragraph (b) to read as follows:

§ 716–1 Basis and scope.

* * * * *

(b) *Scope.* This part establishes standards for group health plans, and health insurance issuers offering group or individual health insurance coverage with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities.

■ 12. Section 2590.716–2 is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 2590.716–2 Applicability.

(a) *In general.* (1) 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.

(2) The requirements in §§ 54.9816–8T and 54.9817–2T apply to certified IDR entities and 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 2590.716–8, 2590.717–1, 2590.717–2 and 2590.722 do not apply to the following:

* * * * *

■ 13. Section 2590.716–8 is added to read as follows:

§ 2590.716–8 Independent dispute resolution process.

(a) *Scope and definitions—(1) Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 2590.716–3 of

this part apply to this section.

Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(1) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(2) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(3) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this section, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(1) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(2) The unauthorized person who used the IIHI or to whom the disclosure was made;

(3) Whether the IIHI was actually acquired or viewed; and

(4) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity, or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation,

partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816-4T, § 2590.716-4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816-T, § 2590.716-5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817-1T, § 2590.717-1, or 45 CFR 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 2590.716-3;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general*. With respect to an item or service that meets the requirements of

paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content*. The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner*. The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(1) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(2) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general*. With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating*

providers and facilities. A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(1) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816-4T(c)(2)(i), § 2590.716-4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816-4T(c)(2)(ii), § 2590.716-4(c)(2)(ii), or 45 CFR 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(2) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(3) State where the qualified IDR item or service was furnished;

(4) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(5) Preferred certified IDR entity;

(6) An attestation that the items and services under dispute are qualified IDR items or services;

(7) Qualifying payment amount;

(8) Information about the qualifying payment amount as described in § 2590.716-6(d); and

(9) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied –

(1) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(2) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined

under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(1) Name of the certified IDR entity;

(2) The certified IDR entity number; and

(3) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also

provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of Health and Human Services and Secretary of the Treasury, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.*

After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue*

negotiations—(i) In general. If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or

service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services, not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services—(i) In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items

and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service—(i) Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(1) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(2) Information requested by the certified IDR entity relating to the offer.

(3) The following additional information, as applicable—

(i) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(ii) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(iii) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured; and

(iv) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs

(c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(1) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(2) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(3) The acuity of the participant, or beneficiary, receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(4) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(5) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the issuer. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the issuer.

(2) *Conclusion.* In this *Example 1*, the nonparticipating provider has submitted additional information. However, this

information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the issuer. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The issuer submits the qualifying payment amount as its offer with no additional information.

(2) *Conclusion.* In this *Example 2*, the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to

the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The issuer submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(2) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the issuer's offer.

(D) *Example 4—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The issuer submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The issuer submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(2) *Conclusion.* In this *Example 4*, both the nonparticipating provider and issuer submitted information that is credible and that may be considered by the certified IDR entity. However, only the issuer provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the issuer has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the issuer's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under

paragraphs (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination—(A) Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(1) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(2) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by

the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1), pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR

entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States, or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for

example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IHI, only to perform:

(1) The certified IDR entity's required duties described in this section; and

(2) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (1) The certified IDR entity must ensure the confidentiality of all IHI it creates, obtains, maintains, stores, and transmits;

(2) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(3) The certified IDR entity must ensure that IHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier;

(4) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(1) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(2) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(3) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(i) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(ii) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(iii) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(iv) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(v) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(4) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and

understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(vii)(A) and (B) of this section as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(1) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(2) A description of the circumstances that require the alternative fee; and

(3) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, written approval to charge the fee documented in the certified IDR

entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) *Conflict-of-interest standards.* In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in

writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation—*
(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human

Services, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification—*(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Health and Human Services;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During

this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process—(1) Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances—(1) General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension

is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

■ 14. Section 2590.717–2 is added to read as follows:

§ 2590.717–2 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 2590.716–3 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process—(1) In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 2590.716–8, except that references in § 2590.716–8 to the additional circumstances in § 2590.716–8(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605)

for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 2590.716–8(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 2590.716–8(c)(4)(ii) of this part (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 2590.716–8(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 2590.716–8(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 2590.716–8(c)(4)(ii) of this part (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as

applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 2590.716–8(d)(1) of this part (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *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 set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147 and 149 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 15. The authority citation for part 147 continues 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.

■ 16. Section 147.136 is amended by:

■ a. Revising paragraphs (a)(1), (c)(2)(i), and (d)(1)(i)(A) and (B);

■ b. Adding paragraph (d)(1)(i)(C);

■ c. Adding Examples 3 through 7 to paragraph (d)(1)(ii); and

■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1)

Scope—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 147.140. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

* * * * *

(c) * * *

(2) * * *

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise

billing and cost-sharing protections under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant, beneficiary, or enrollee is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of PHS Act section 2726 and §§ 146.136 and 147.160, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant, beneficiary, or enrollee fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) * * *

Example 3. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 149.110 do not apply because the treatment did not involve “emergency services” within the meaning of § 149.110(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing

requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3*, the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 149.110. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 4. (i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 149.120. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 149.120.

(ii) *Conclusion.* In this *Example 4*, whether the plan was required to decide the claim in a manner consistent with the requirements of § 149.120 involves considering whether the plan complied with § 149.120, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 149.110(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 149.110.

(ii) *Conclusion.* In this *Example 5*, whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 149.110(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 149.120(a) and the fact that those protections may not be waived for neonatology services under § 149.120(b).

(ii) *Conclusion.* In this *Example 6*, medical judgment is necessary to determine whether the correct code was used and compliance with § 149.120(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 149.120(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 149.120(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are

greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 149.120(a) and (b).

(ii) *Conclusion.* In this *Example 7*, consideration of whether the plan complied with the requirements in § 149.120(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *
(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans and grandfathered individual market policies, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 17. The authority citation for part 149 is amended to read as follows:

Authority: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

■ 18. Section 149.10 is amended by revising paragraph (b) to read as follows:

§ 149.10 Basis and scope.

* * * * *
(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. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities. This part also establishes a Patient-Provider Dispute Resolution Process and standards for certifying Selected Dispute Resolution entities.

■ 17. Section 149.20 is amended by adding paragraphs (a)(3) and (4) and

revising paragraph (b) introductory text to read as follows:

§ 149.20 Applicability.

(a) * * *
(3) The requirements in subpart F of this part apply to certified IDR entities, health care providers, health care facilities, and providers of air ambulance services and 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.

(4) The requirements in subpart G of this part apply to Selected Dispute Resolution Entities, health care providers, providers of air ambulance services, health care facilities and uninsured (or self-pay) individuals, as defined in subpart G.

(b) *Exceptions.* The requirements in subparts B, D, E, and F of this part do not apply to the following:

* * * * *
■ 18. Section 149.450 is amended by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 149.450 Complaint process for balance billing and good faith estimates 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 or subpart G of this part, which may warrant an investigation.

(2) * * *
(i) *Complaint* means a communication, written, or oral, that indicates there has been a potential violation of the requirements under this subpart or subpart G of this part, whether or not a violation actually occurred.

* * * * *
■ 20. Subpart F, consisting of §§ 149.510 and 149.520, is added to read as follows:

Subpart F—Independent Dispute Resolution Process

§ 149.510 Independent dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of

air ambulance services (as applicable), and a group health plan or health insurance issuer offering group or individual health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.30 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) *Breach* excludes:

(1) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(2) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(3) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this definition, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v)

of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IHI has been compromised based on a risk assessment encompassing at least the following factors:

(1) The nature and extent of the IHI involved, including the types of identifiers and the likelihood of re-identification;

(2) The unauthorized person who used the IHI or to whom the disclosure was made;

(3) Whether the IHI was actually acquired or viewed; and

(4) The extent to which the risk to the IHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Labor and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional

relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan or coverage administrator, plan or coverage fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or
(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or

participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816-4T, 29 CFR 2590.716-4, or § 149.110, as applicable, for which the conditions of § 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816-5T, 29 CFR 2590.717-5, or § 149.120, as applicable, for which the conditions of § 149.420(c)-(i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817-1T, 29 CFR 2590.717-1, or § 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 149.30;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIIH* means IIIH that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1)

Determination of payment amount through open negotiation—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(1) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(2) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network

rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(1) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816-4T(c)(2)(i), 29 CFR 2590.716-4(c)(2)(i), or § 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816-4T(c)(2)(ii), 29 CFR 2590.716-4(c)(2)(ii), or § 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(2) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(3) State where the qualified IDR item or service was furnished;

(4) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(5) Preferred certified IDR entity;

(6) An attestation that the items and services under dispute are qualified IDR items or services;

(7) Qualifying payment amount;

(8) Information about the qualifying payment amount as described in § 149.140(d); and

(9) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(1) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(2) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity

selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(1) Name of the certified IDR entity;

(2) The certified IDR entity number; and

(3) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) {Reserved}

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a

certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of the Treasury and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) of this section within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the

Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service—(i) Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(1) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(2) Information requested by the certified IDR entity relating to the offer.

(3) The following additional information, as applicable—

(i) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(ii) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(iii) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(iv) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide

the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(1) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(2) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(3) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(4) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(5) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the issuer. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the issuer.

(2) *Conclusion.* In this *Example 1*, the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the issuer. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The issuer submits the qualifying payment amount as its offer with no additional information.

(2) *Conclusion.* In this *Example 2*, the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of

training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The issuer submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(2) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the issuer's offer.

(D) *Example 4—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The issuer submits credible information demonstrating that the patent for the item that is the subject of the payment

determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The issuer submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(2) *Conclusion.* In this *Example 4*, both the nonparticipating provider and issuer submitted information that is credible and that may be considered by the certified IDR entity. However, only the issuer provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the issuer has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the issuer's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or

demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination—(A) Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(1) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(2) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process

with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process—(1) Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1) of this section, pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance

published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity—(1) In general.* In order to be selected under paragraph (c)(1) of this section—(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in

paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(1) The certified IDR entity's required duties described in this section; and

(2) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (1) The certified IDR entity must ensure the confidentiality of

all IIHI it creates, obtains, maintains, stores, and transmits;

(2) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(3) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier.

(4) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(1) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(2) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(3) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(i) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(ii) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(iii) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth,

home address, account number, diagnosis, disability code, or other types of information were involved);

(iv) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(v) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(4) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(v)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(1) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(2) A description of the circumstances that require the alternative fee; and

(3) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) Conflict-of-interest standards. In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute

determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation—*
(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the

Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) *Effect on certification under petition.* Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification—*(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the

Treasury, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must

submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process—(1) Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances—(1) General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *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, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

§ 149.520 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 149.30 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process—(1) In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 149.510(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 149.510(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 149.510(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the

payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 149.510(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(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.

■ 21. Subpart G, consisting of §§ 149.610 and 149.620, is added to read as follows:

Subpart G—Protection of Uninsured or Self-Pay Individuals

§ 149.610 Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.

(a) *Scope and definitions—(1) Scope.* This section sets forth requirements for health care providers and health care facilities related to the issuance of good faith estimates of expected charges for uninsured (or self-pay) individuals (or their authorized representatives), upon request or upon scheduling an item or service.

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) *Authorized representative* means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented in the good faith estimate,

unless such provider or employee is a family member of the uninsured (or self-pay) individual.

(ii) *Convening health care provider or convening health care facility (convening provider or convening facility)* means the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service.

(iii) *Co-health care provider or co-health care facility (co-provider or co-facility)* means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service.

(iv) *Diagnosis code* means the code that describes an individual's disease, disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set.

(v) *Expected charge* means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

(vi) *Good faith estimate* means a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

(vii) *Health care facility (facility)* means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

(viii) *Health care provider (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,

including a provider of air ambulance services.

(ix) *Items or services* has the meaning given in 45 CFR 147.210(a)(2).

(x) *Period of care* means the day or multiple days during which the good faith estimate for a scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, including the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.

(xi) *Primary item or service* means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit.

(xii) *Service code* means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG) or National Drug Codes (NDC) code sets.

(xiii) *Uninsured (or self-pay) individual* means:

(A) An individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or

(B) An individual who has benefits for such item or service under a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage.

(b) *Requirements of providers and facilities*—(1) *Requirements for convening providers and convening facilities.* A convening provider or convening facility must determine if an individual is an uninsured (or self-pay) individual by:

(i) Inquiring if an individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social

Security Act), or a health benefits plan under chapter 89 of title 5, United States Code;

(ii) Inquiring whether an individual who is enrolled in a group health plan, or group or individual health insurance coverage offered by a health insurance issuer or a health benefits plan under chapter 89 of title 5, United States Code is seeking to have a claim submitted for the primary item or service with such plan or coverage; and

(iii) Informing all uninsured (or self-pay) individuals of the availability of a good faith estimate of expected charges upon scheduling an item or service or upon request; information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be:

(A) Written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur;

(B) Orally provided when scheduling an item or service or when questions about the cost of items or services occur; and

(C) Made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with such convening provider or convening facility.

(iv) Convening providers and convening facilities shall consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate;

(v) Upon the request for a good faith estimate from an uninsured (or self-pay) individual or upon scheduling a primary item or service to be furnished for such an individual, the convening provider or convening facility must contact, no later than 1 business day of such scheduling or such request, all co-providers and co-facilities who are reasonably expected to provide items or services in conjunction with and in support of the primary item or service and request that the co-providers or co-facilities submit good faith estimate information (as specified in paragraphs (b)(2) and (c)(2) of this section) to the convening provider or facility; the request must also include the date that good faith estimate information must be received by the convening provider or facility;

(vi) Provide a good faith estimate (as specified in paragraph (c)(1) of this section) to uninsured (or self-pay)

individuals within the following timeframes:

(A) When a primary item or service is scheduled at least 3 business days before the date the item or service is scheduled to be furnished: Not later than 1 business day after the date of scheduling;

(B) When a primary item or service is scheduled at least 10 business days before such item or service is scheduled to be furnished: Not later than 3 business days after the date of scheduling; or

(C) When a good faith estimate is requested by an uninsured (or self-pay) individual: Not later than 3 business days after the date of the request.

(vii) A convening provider or convening facility must provide an uninsured (or self-pay) individual who has scheduled an item or service with a new good faith estimate if a convening provider, convening facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a good faith estimate (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling; a new good faith estimate must be issued to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished.

(viii) If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before the item or service is scheduled to be furnished, the replacement provider or facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the items or services being furnished that was provided by the replaced provider or facility.

(ix) For good faith estimates provided upon request of an uninsured (or self-pay) individual, upon scheduling of the requested item or service, the convening provider or convening facility must provide the uninsured (or self-pay) individual with a new good faith estimate for the scheduled item or service within the timeframes specified in paragraphs (b)(1)(vi)(A) and (B) of this section; and

(x) A convening provider or convening facility may issue a single good faith estimate for recurring primary items or services if the following requirements are met, in addition to the requirements under this section:

(A) The good faith estimate for recurring items or services must include, in a clear and understandable manner, the expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services); and

(B) The scope of a good faith estimate for recurring primary items or services must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months (or as specified under paragraph (b)(vii) of this section), a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate, and communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

(2) *Requirements for co-providers and co-facilities.* (i) Co-providers and co-facilities must submit good faith estimate information (as specified in paragraph (c)(2) of this section) upon the request of the convening provider or convening facility. The co-provider or co-facility must provide, and the convening provider or convening facility must receive, the good faith estimate information no later than 1 business day after the co-provider or co-facility receives the request from the convening provider or convening facility.

(ii) Co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities).

(iii) If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

(iv) In the event that an uninsured (or self-pay) individual separately schedules or requests a good faith

estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) of this section for issuing a good faith estimate to an uninsured (or self-pay) individual.

(c) *Content requirements of a good faith estimate issued to an uninsured (or self-pay) individual.* (1) A good faith estimate issued to an uninsured (or self-pay) individual must include:

(i) Patient name and date of birth;

(ii) Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);

(iii) Itemized list of items or services, grouped by each provider or facility, reasonably expected to be furnished for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including:

(A) Items or services reasonably expected to be furnished by the convening provider or convening facility for the period of care; and

(B) Items or services reasonably expected to be furnished by co-providers or co-facilities (as specified in paragraphs (b)(2) and (c)(2) of this section);

(iv) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(v) Name, National Provider Identifier, and Tax Identification Number of each provider or facility represented in the good faith estimate, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;

(vi) List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that includes the following information: Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services; notification that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon

request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;

(viii) A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;

(ix) A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate regarding items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate; and

(x) A disclaimer that informs the uninsured (or self-pay) individual of the uninsured (or self-pay) individual's right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in § 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

(xi) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

(2) [Reserved]

(d) *Content Requirements for Good Faith Estimate Information Submitted by Co-Providers or Co-Facilities to Convening Providers or Convening Facilities.* (1) Good faith estimate information submitted to convening providers or convening facilities by co-providers or co-facilities for inclusion in the good faith estimate (described in paragraph (c)(1) of this section) must include:

(i) Patient name and date of birth;

(ii) Itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in

conjunction with the primary item or service as part of the period of care;

(iii) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(iv) Name, National Provider Identifiers, and Tax Identification Numbers of the co-provider or co-facility, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and

(v) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

(2) [Reserved]

(e) *Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals.* (1) A good faith estimate must be provided in written form either on paper or electronically, pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes described in paragraph (b) of this section. Good faith estimates provided electronically must be provided in a manner that the uninsured (or self-pay) individual can both save and print. A good faith estimate must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.

(2) To the extent that an uninsured (or self-pay) individual requests a good faith estimate in a method other than paper or electronically (for example, by phone or orally in person), the convening provider may orally inform the uninsured (or self-pay) individual of information contained in the good faith estimate using the method requested by the uninsured (or self-pay) individual; however, in order for a convening provider or convening facility to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate to the uninsured (or self-pay) individual in written form as specified in paragraph (e)(1) of this section.

(f) *Additional compliance provisions.*

(1) A good faith estimate issued to uninsured (or self-pay) individual under this section is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record. Convening providers and convening facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay)

individual upon the request of the uninsured (or self-pay) individual.

(2) Providers or facilities that issue good faith estimates issued under State processes that do not meet the requirements set forth in this section fail to comply with the requirements of this section.

(3) A provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(4) To the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, the provider or facility will not fail to comply with this section if it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(g) *Applicability*—(1) *Applicability date.* The requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 or for good faith estimates required to be provided in connection with items or services scheduled on or after January 1, 2022.

(2) *Applicability with other laws.* Nothing in this section alters or otherwise affects a provider's or facility's requirement to comply with other applicable State or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the

extent a state law prevents the application of this section.

§ 149.620 Requirements for the patient-provider dispute resolution process.

(a) *Scope and definitions*—(1) *Scope*. This section sets forth requirements for the patient-provider dispute resolution process, under which an uninsured (or self-pay) individual, with respect to eligible items or services under paragraph (b) of this section, may submit notification under paragraph (c) of this section to initiate the patient-provider dispute resolution process. This section sets forth in paragraph (d) of this section the certification requirements for a dispute resolution entity to become a Selected Dispute Resolution (SDR) entity contracted to resolve the patient-provider dispute, and the process for HHS to select SDR entities for patient-provider disputes under paragraph (e) of this section. This section sets forth in paragraph (f) the process and requirements regarding how SDR entities will determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility. This section also sets forth requirements for an administrative fee under paragraph (g) of this section and minimum requirements under paragraph (h) of this section for states that wish to establish processes for performing patient-provider dispute resolution in place of the Federal process.

(2) *Definitions*. Unless otherwise stated, the definitions in § 149.610(a)(2) apply to this section. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach*, *individually identifiable health information (IIHI)*, and *unsecured IIHI* also apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Billed charge(s)* means the amount billed by a provider or facility for an item or service.

(ii) *Substantially in excess* means, with respect to the total billed charges by a provider or facility, an amount that is at least \$400 more than the total amount of expected charges listed on the good faith estimate for the provider or facility.

(iii) *Total billed charge(s)* means the total of billed charges, by a provider or facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

(b) *Eligibility for patient-provider dispute resolution*—(1) *In general*. In

general, an item or service provided by a convening provider, convening facility, co-provider, or co-facility is eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under § 149.610.

(2) *Special rule for co-provider or co-facility substitution*. If a co-provider or co-facility that provided an estimate of the expected charge for an item or service in the good faith estimate is substituted for a different co-provider or co-facility, an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with a new good faith estimate in accordance with § 149.610(b)(2), then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charge for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

(c) *Initiation of the Patient Provider dispute resolution process*—(1) *In general*. With respect to an item or service that meets the requirements in paragraph (b) of this section, an uninsured (or self-pay) individual (or their authorized representative, excluding any providers directly represented in the good faith estimate, providers associated with these providers, non-clinical staff associated with these providers, or individuals employed or associated with a facility that had included services in the good faith estimate) may initiate the patient-provider dispute resolution process by submitting a notification (initiation notice) to HHS as specified in paragraph (c)(2) of this section postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount

and in a manner that will be clarified in guidance by HHS.

(2) *Initiation notice*—(i) *Content*. The notice to initiate the patient-provider dispute resolution process must include:

(A) Information sufficient to identify the item or service under dispute, including the date the item or service was provided, and a description of the item or service;

(B) A copy of the provider or facility bill for the item and service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(C) A copy of the good faith estimate for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(D) If not included on the good faith estimate, contact information of the provider or facility involved, including, if available, name, email address, phone number, and mailing address;

(E) The State where the items or services in dispute were furnished; and

(F) The uninsured (or self-pay) individual's communication preference, through the Federal IDR portal, or electronic or paper mail.

(ii) *Manner*. The uninsured (or self-pay) individual or their authorized representative must submit the initiation notice, to the Secretary by submitting the notice via the Federal IDR portal, electronically, or on paper, in the form and manner specified by the Secretary. The date of initiation of the patient-provider dispute resolution process will be the date the Secretary receives such initiation notice. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(3) *Notification of SDR entity receipt*. Upon receipt of the initiation notice described in paragraph (c)(1) of this section, HHS will select an SDR entity according to the process described in paragraph (e) of this section. Upon selection, the SDR entity will, through the Federal IDR portal, or electronic or paper mail, notify the uninsured (or self-pay) individual, and the provider or facility that a patient-provider dispute resolution request has been received and is under review. Such notice shall also include:

(i) Sufficient information to identify the item or service under dispute;

(ii) The date the initiation notice was received;

(iii) Notice of the additional requirements for providers or facilities specified in paragraphs (c)(5) and (6) of this section while the patient-provider dispute resolution process is pending; and

(iv) Information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist the individual with the dispute.

(4) *Validation of initiation notice.* After the selection of the SDR entity, as described in paragraph (c)(2) of this section, the SDR entity shall review the initiation notice to ensure the items or services in dispute meet the eligibility criteria described in paragraph (b) of this section and the initiation notice contains the required information described in paragraph (c)(2). The SDR entity will notify the uninsured (or self-pay) individual of the outcome of the review, including, if applicable, providing the individual with 21 calendar days to submit supplemental information when the initiation notice is determined to be incomplete or the items or services are determined ineligible for dispute resolution.

(i) If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the item or service has been determined eligible for dispute resolution. The SDR entity shall request the provider or facility provide the information described in paragraph (f)(2) of this section within 10 business days.

(ii) If the SDR entity determines that the item or service does not meet the eligibility criteria or that the initiation notice does not contain the required information, the SDR entity will provide an insufficiency notice to the uninsured (or self-pay) individual of the determination and the reasons for the determination and will notify the uninsured (or self-pay) individual that the individual may submit supplemental information, postmarked within 21 calendar days, to resolve any deficiencies identified. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar-day extension will be granted so that the individual will have a total of 35 calendar days to submit supplemental information.

(5) *Prohibitions on collections.* While the patient-provider dispute resolution

process is pending, the provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded.

(6) *Prohibitions on retributive action.* The provider or facility must not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service.

(d) *Certification of SDR entities—(1) In general.* The Secretary shall contract with and certify only that number of SDR entities the Secretary believes will be necessary to timely resolve the volume of patient-provider disputes. As part of the contract process with HHS, a potential SDR entity must satisfy the Federal IDR entity certification criteria specified in § 149.510(e), subject to the exceptions set forth in paragraphs (d)(2) of this section. In addition, the SDR entity must also meet the conflict-of-interest mitigation policy requirements specified in paragraph (d)(3) of this section. Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements.

(2) *Exception for SDR entity certification.* With respect to certified IDR entity requirements that do not apply to an SDR entity, potential SDR entities are not required to make the following submissions:

(i) Information regarding the service area(s) for which the entity will arbitrate cases, however, a potential SDR entity will need to submit information on their ability to operate nationwide through the contract process;

(ii) Fee schedule for batched and non-batched claims;

(iii) Policies and procedures to hold dispute resolution entity fees in a trust or escrow account, however, a potential SDR entity must submit policies and procedures to hold administrative fees, as described in paragraph (g) of this section, and remit them to HHS in a manner specified by HHS.

(3) *Conflict of interest mitigation policies.* A potential SDR entity must also provide additional information on the SDR entity's conflict-of-interest policies and procedures, including outlining a mitigation plan in the event of an entity-level conflict of interest, under which no dispute resolution

personnel affiliated with the SDR entity can fairly and impartially adjudicate a case, in compliance with the standards in Federal Acquisition Regulation-subpart 9.5 (48 CFR subpart 9.5). Such conflict of interest mitigation plan could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for the case.

(e) *Selection of an SDR entity.* (1) After the Secretary has received the initiation notice as described in paragraph (c) of this section, the Secretary will assign an SDR entity that is certified and contracted under paragraph (d) of this section to conduct the dispute resolution process for the item or service. Upon receiving an assignment from the Secretary to make a determination for an item or service as described in paragraph (c)(3) of this section, the SDR entity shall ensure that no conflict of interest exists, and in such case, shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity.

(2) Should a conflict of interest exist, the SDR entity must submit notice to the Secretary of such conflict no later than 3 business days following selection by the Secretary. The Secretary will then automatically select a new SDR entity to conduct the patient-provider dispute resolution process for the item or service. In the event that no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan as described in paragraph (d)(3) of this section. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed. In the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

(3) Conflict of interest means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when an SDR entity is:

(i) A provider or a facility;

(ii) An affiliate or a subsidiary of a provider or facility;

(iii) An affiliate or subsidiary of a professional or trade association representing a provider or facility; or

(iv) An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.

(4) Either party to the dispute resolution process (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days receiving the attestation.

(f) *Payment determination for Patient-Provider dispute resolution*—(1)

Determination of payment amount through settlement—(i) *In general.* If the parties to a dispute resolution process agree on a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the dispute resolution process has been initiated but before the date on which a determination is made under paragraph (f)(3) of this section, the provider or facility will notify the SDR entity through the Federal IDR Portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date of such settlement, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount equal to at least half the amount of the administrative fee paid as set forth in paragraph (g) of this section. Once the SDR entity receives the settlement notice, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

(ii) *Treatment of payments made prior to determination.* Payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) prior to a determination under paragraph (f)(3) of this section does not demonstrate agreement by the

uninsured (or self-pay) individual to settle at that amount or any other amount.

(2) *Determination of payment amount through the patient-provider dispute resolution process*—(i) *In general.* With respect to an item or service to which an agreement described in paragraph (f)(1) of this section does not apply, not later than 10 business days after the receipt of the selection notice from the SDR entity described in paragraph (c)(4)(i) of this section, the provider or facility must submit to the SDR entity:

(A) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(B) A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and

(C) If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Timeframe for SDR entity determination.* Not later than 30 business days after receipt of the information described in paragraph (f)(2)(i) of this section, the SDR entity must make a determination regarding the amount to be paid by such uninsured (or self-pay) individual, taking into account the requirements in paragraph (f)(3) of this section.

(3) *Payment determination by an SDR entity*—(i) *In general.* The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual, and the provider or the facility, and make a separate determination for each unique item or service charged as to whether the provider or facility has provided credible information to demonstrate that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Definition of credible information.* Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

(iii) *Payment determination process.* (A) For an item or service that appears on the good faith estimate:

(1) If the billed charge is equal to or less than the expected charge for the item or service in the good faith estimate, the SDR entity must determine the amount to be paid for the item or service as the billed charge.

(2) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility does not provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid for the item or service to be equal to the expected charge for the item or service in the good faith estimate.

(3) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility provides credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine as the amount to be paid for the item or service, the lesser of:

(i) The billed charge; or

(ii) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in § 149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in § 149.140(a)(3) using the methodology described in § 149.140(c)(3), except that in cases where the amount determined by an independent database is determined to be less than the expected charge for the item or service listed on the good faith estimate, the amount to be paid will equal to the expected charge for the item or service listed on the good faith estimate. When comparing the billed charge with the amount contained in an independent database, the SDR entity

should account for any discounts offered by the provider or facility.

(B) For an item or service that does not appear on the good faith estimate (new item or service):

(1) If the SDR entity determines that the information submitted by the provider or facility does not provide credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine that amount to be paid for the new item or service to be equal to \$0.

(2) If the SDR entity determines that the information submitted by the provider or facility provides credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid for the new item or service, the lesser of:

(i) The billed charge; or

(ii) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in § 149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in § 149.140(a)(3) using the methodology described in § 149.140(c)(3). When comparing the billed charge with the amounts contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(C) To calculate the final payment determination amount, the SDR entity must add together the amounts to be paid for all items or services subject to the determination. In cases where the final amount determined by the SDR entity is lower than the billed charges, the SDR entity must reduce the total amount determined by the amount paid by the individual for the administrative fee described in paragraph (g) of this section to calculate the final payment determination amount to be paid by the individual for the items or services.

Once the final payment determination amount has been calculated, the SDR entity will inform the uninsured (or self-pay) individual and the provider or facility, through the Federal IDR portal, or by electronic or paper mail, of such determination, the determination

amount and the SDR entity's justification for making the determination. After such notification is made, the SDR entity will close the case.

(4) *Effects of determination.* A determination made by an SDR entity under this paragraph (f) will be binding upon the parties involved, in the absence of a fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, the uninsured (or self-pay) individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount.

(g) *Costs of patient-provider dispute resolution process*—(1) *Administrative fee to participate in the patient-provider dispute resolution process.* (i) The uninsured (or self-pay) individual shall pay to the SDR entity the administrative fee amount described in section (g)(2) of this section at the initiation of the patient-provider dispute resolution process described in paragraph (c) of this section. The SDR entity shall remit all administrative fees collected to the Secretary upon receiving an invoice from HHS.

(ii) In cases where the SDR entity issues a determination and the provider or facility is the non-prevailing party as described in section (g)(1)(iv) of this section, the provider or facility must pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iii) If the SDR entity issues a determination and the provider or facility is the prevailing party as described in paragraph (g)(1)(iv) of this section, the provider or facility is not required to pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iv) For purposes of paragraphs (g)(1)(ii) and (iii) of this section, the prevailing party is the provider or facility in cases where the SDR entity determines the amount to be paid as equal to the billed charges; and the prevailing party is the uninsured (or self-pay) individual in cases where the

SDR entity determines the amount to be paid as less than the billed charges.

(v) Allocation of administrative fee in the case of settlement. In case of a settlement described in paragraph (f)(1) of this section, the provider or facility must pay an amount equal to half of the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied to the final settlement amount. The provider or facility will document in the settlement notice described in paragraph (f)(1) that it has applied a payment reduction of at least half of the administrative fee amount to the uninsured (or self-pay) individual's settlement amount.

(2) Establishment of the administrative fee. The amount of the administrative fee described in paragraph (g)(1) of this section will be specified by the Secretary through guidance.

(h) *Deferral to State patient-provider dispute resolution processes*—(1) *In general.* If the Secretary determines that a state law provides a process to determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility, and that such process meets or exceeds the requirements in paragraph (h)(2) of this section, the Secretary shall defer to the State process and direct any patient-provider dispute resolution requests received from uninsured (or self-pay) individuals in such state to the State process to adjudicate the dispute resolution initiation request.

(2) *Minimum Federal requirements.* A State process described in paragraph (h)(1) of this section shall at a minimum:

(i) Be binding, unless the provider or facility offer for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;

(ii) Take into consideration a good faith estimate, that meets the minimum standards established in § 149.160, provided by the provider or facility to the uninsured (or self-pay) individual;

(iii) If the State has a fee charged to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the Federal administrative fee established in paragraph (g) of this section; and

(iv) Have in place conflict-of-interest standards that at a minimum meets the requirements set forth in paragraphs (d) and (e) of this section.

(3) *HHS determination of State process.* HHS will review the State process to determine whether it meets or exceeds the minimum Federal requirements set forth in paragraph

(h)(2) of this section—HHS will communicate with the state and determine whether such process meets or exceeds such requirements. HHS will notify the state in writing of such determination.

(4) *HHS review of State process.* HHS will review changes to the State process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards set forth in this section.

(5) *State process termination.* In the event that the State process is terminated, or HHS determines that the State process no longer meets the minimum Federal requirements described in paragraph (h)(2) of this section, HHS will make the Federal process available to uninsured (or self-

pay) individuals in that State to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum Federal requirements.

(i) *Extension of time periods for extenuating circumstances—(1) In general.* The time periods specified in this section (other than the time for payment of the administrative fees under paragraph (d)(2) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The time periods specified in this

section may be extended in the case of extenuating circumstances at HHS' discretion. The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, or electronic or paper mail if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(j) *Applicability date.* The provisions of this section are applicable to uninsured (or self-pay) individuals; providers (including providers of air ambulance services) and facilities; and SDR entities, generally beginning on or after January 1, 2022. The provisions regarding SDR entity certification in paragraphs (a) and (d) of this section, are applicable beginning on October 7, 2021.

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42 CFR Part 59

Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN 0937-AA11

Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Office of Population Affairs (OPA) in the Office of the Assistant Secretary for Health issues this final rule to revise the regulations that govern the Title X family planning program (authorized by Title X of the Public Health Service Act) by readopting the 2000 regulations, with several revisions to ensure access to equitable, affordable, client-centered, quality family planning services for clients, especially low-income clients. The effect of this 2021 final rule is to revoke the requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities, thereby reversing the negative public health consequences of the 2019 regulations. OPA also makes several revisions to the 2000 regulations to increase access to equitable, affordable, client-centered, quality family planning services.

DATES: This rule is effective November 8, 2021.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: As described in the 2021 Notice of Proposed Rulemaking (NPRM) (86 FR 19812, April 15, 2021), the Department proposed to revoke the 2019 Title X regulations (84 FR 7714, March 4, 2019) and readopt the 2000 regulations (65 FR 41270, July 3, 2000) with 14 revisions and 10 technical corrections. Revisions were proposed to 59.2, 59.5(a)(1), 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(a)(12), 59.5(a)(13), 59.5(b)(1), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, 59.10,

and 59.11. Technical corrections were proposed to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), 59.8, and 59.12. HHS received comments on all of the revisions proposed in the NPRM, except the revision to 59.11. In addition, the Department received comments on three of the 10 technical corrections, including the technical corrections to 59.5(a)(4), 59.5(a)(5), and 59.12.

Based on the comments received in response to the NPRM, the Department adopts eight of the revisions initially proposed in the NPRM and nine of the technical corrections initially proposed in the NPRM as final without additional changes. This includes the revisions to 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, and 59.11. This also includes the technical corrections to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), and 59.8. Further, based on the comments received in response to the NPRM and a subsequent, new interpretation by the Department since the NPRM was issued, the final rule includes nine additional revisions and six additional technical corrections to what was proposed in the NPRM. The nine revisions include (a) additional modifications to four of the provisions initially revised in the NPRM (59.2, 59.5(a)(1), 59.5(b)(1), and 59.10); (b) additional modifications to one of the provisions with a technical correction in the NPRM (59.5(a)(4)); (c) removal of three of the revised provisions in the NPRM (59.5(a)(12), 59.5(a)(13), and 59.12); and (d) revisions to one provision not originally proposed for revision in the NPRM (59.5(b)(6)). The six additional technical corrections include minor clarifications to 59.2, 59.5(a)(1), 59.5(a)(4), and 59.6 and two technical corrections to 59.5(b)(7) and 59.7 to reflect inclusive language.

Detailed descriptions of all revisions, modifications, and technical corrections are included later in this final rule. In addition to revoking the 2019 rule, this final rule includes the following revisions to the 2000 rule: Adding several new definitions; requiring sites that do not offer a broad range of contraceptive methods on-site to provide a prescription to the client for their method of choice or referrals, as requested; requiring that family planning services be client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and capable of ensuring equitable and quality service delivery; clarifying requirements around billing practices and income verification; enabling a broader range of clinical service providers to direct family

planning services and to provide consultation for medical services related to family planning; clarifying the intent of community education; clarifying the purpose and responsibilities of the Information and Education Advisory Committee; including referral for primary healthcare providers; expanding the grant review criteria to address equity; including language to safeguard client confidentiality; and removing the list of other applicable regulations from the regulatory text.

The Secretary of the Department of Health and Human Services (the Secretary) issues the below regulations establishing requirements for recipients of family planning services grants under section 1001 of the Public Health Service (PHS) Act, 42 U.S.C. 300. The rules below adopt, with the modifications described above, the regulations proposed for public comment on April 15, 2021 at 86 FR 19812. They accordingly revoke the 2019 final rule, *Compliance with Statutory Program Integrity Requirements*, promulgated on March 4, 2019 (84 FR 7714).

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I. Background

As discussed in the NPRM (86 FR 19812, April 15, 2021), in 2019, the Secretary issued a final rule for the Title X program titled *Compliance with Statutory Program Integrity Requirements*, which substantially revised the longstanding policies and interpretations defining what abortion-related activities were permissible under the program, given Title X's statutory prohibition on abortion services. That statutory prohibition, section 1008 (42 U.S.C. 300a-6), provides that “[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.” The 2000 regulations, which were in effect prior to the 2019 regulations and which reflected compliance standards that had been in effect for nearly the entirety of the Title X program, had been widely accepted by grantees, had enabled the Title X program to operate successfully, and had not resulted in any litigation.

The rules issued on March 4, 2019 (84 FR 7714): (1) Required strict physical and financial separation between abortion-related activities and Title X project activities, (2) required significant reporting by Title X grantees in grant applications and required reports about all subrecipients, referral agencies, or other partners who receive Title X funds, (3) removed the requirement for pregnancy options counseling upon request and permitted nondirective counseling only by an advanced practice provider, (4) prohibited Title X-funded entities from referring for abortion, while requiring referral for prenatal care, regardless of a client's request, and (5) required providers to maintain detailed records on adolescent

clients, including age of their sexual partners and specific actions taken to encourage family participation.

In the 2019 rule, the Department stated that it “believes the provisions of this final rule provide much needed clarity regarding the Title X program's role as a family planning program that is statutorily forbidden from paying for abortion and funding programs/projects where abortion is a method of family planning. The Department believes that the 2000 regulations fostered an environment of ambiguity surrounding appropriate Title X activities.” 84 FR at 7721 (March 24, 2019). This belief about the ambiguity, however, lacked any specific evidence. OPA closely monitors Title X grantee compliance through regular grant reports, compliance monitoring visits, and legally required audits, and it has done so since the beginning of the program. Close oversight of Title X grantees for decades uncovered no misallocation of Title X funds by grantees. OPA oversight did identify occasional instances where grantees were in need of updating their written policies to clearly reflect the Title X statutory language, but OPA never found any instance where grantees were co-mingling funds with activities not allowed under the statute or regulations.

In response to concerns that the 2019 rule imposed undue and improper restrictions on grantees, the Department recently conducted a fresh review of the factual assertions that accompanied that rule. In particular, the Department carefully reviewed over 30 Government Accountability Office (GAO), Office of the Inspector General (OIG), and Congressional Research Service (CRS) reports involving the Title X program from 1975 to 2021. Directly contradicting the factual assertions accompanying the 2019 rule, that recent review found only minor compliance issues with grantees—and those only in two GAO reports from the 1980s. Those two reports recommended only more specific guidance, not a substantial reworking of the regulations. *See, e.g.*, Comp. Gen. Rep. No GAO/HARD-HRD-82-106 (1982), at 14-15; 65 FR 41270, 41272 (July 3, 2000). While those forty-year-old reports found some confusion among grantees around section 1008, “GAO found no evidence that Title X funds had been used for abortions or to advise clients to have abortions.” Since those reports, there has been no evidence of compliance issues regarding section 1008 by Title X grantees that would justify the greatly increased compliance costs for grantees and oversight costs for the federal government the 2019 rule required.

Experience under the 2019 rule has only underscored these concerns. Based on that experience—which was not and could not have been available to the Department at the time the 2019 rule was promulgated—we have determined that the 2019 rule has led to a diversion of funds from the core purpose of Title X: To provide a broad range of family planning services. Those funds are now being spent on increased infrastructure costs resulting from the separation requirement as well as the micro-level monitoring and reporting now required of grantees. None of these burdensome additional requirements provide discernible compliance benefits, particularly not to public health, and in some instances they are inconsistent with nationally recognized standards of care.

The significant negative public health consequences of the March 4, 2019 rule have become clear over the past two years, and the rule was extremely controversial from the beginning. The rule was immediately challenged in several district courts by 22 states and the District of Columbia, the American Medical Association, Title X grantee organizations, and individual grantees, with support from major medical organizations, including the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Academy of Family Physicians, the Society for Adolescent Health and Medicine, and the Society for Maternal-Fetal Medicine. The 2019 rule was ultimately upheld by an *en banc* Court of Appeals for the Ninth Circuit and enjoined (only as to the state of Maryland) by a district court in Maryland in a decision upheld by the *en banc* Court of Appeals for the Fourth Circuit. Both court of appeals decisions were issued over substantial dissents. In *California v. Azar*, 950 F.3d 1067 (9th Cir. 2020), the Ninth Circuit relied heavily on *Rust v. Sullivan*, 500 U.S. 173 (1991) in upholding the rule. A majority of the *en banc* panel found, consistent with *Rust*, that the Department “could” interpret section 1008 as it did in the 2019 rule, and that nothing in subsequent legislation prevented this reading. *Id.* at 1085. The Ninth Circuit upheld the rule against an arbitrary and capricious challenge, stating “that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better.” *Id.* at 1097 (emphasis in original). Conversely, a majority of the Fourth Circuit found the Department's 2019 rule arbitrary and capricious. *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020). The Fourth

Circuit also held that the 2019 rule violated an annual appropriations rider requiring nondirective counseling, the non-directive mandate.¹

Losing parties in both cases sought review from the Supreme Court in October of 2020. The Court granted certiorari on February 22, 2021, consolidating the cases. No. 20–429. On March 12, 2021, the parties stipulated to dismiss the cases under Supreme Court Rule 46.1.

While courts and judges were split on the ultimate legality of the 2019 rule, evidence of the negative public health consequences of the rule quickly became clear, and significant. After the implementation of the 2019 rule, 19 Title X grantees out of 90 total grantees withdrew from the program. The 19 grantees that withdrew from the Title X program included 11 State Departments of Health and independent Family Planning Associations and eight Planned Parenthood organizations.²

These organizations made clear to the Department in formal correspondence that they relinquished their grants out of concern that the 2019 rule interfered with the patient-provider relationship and compromised their ability to provide quality healthcare to all clients. One organization commented that “the Final Rule makes it impossible for us to provide healthcare and information to patients consistent with medical ethics and evidence-based standards of care.” Another organization stated that the 2019 rule “would fundamentally compromise the relationship our patients have with us as trusted providers of this most personal and private healthcare.” Another organization said that “the new regulations interfere with a healthcare provider’s ability to provide healthcare in accordance with accepted standards of care for reproductive health.” Still another said, “these new rules require our providers to deprive their patients of the information and services they

need to make and carry out fully informed decisions about their reproductive health. Our providers’ ethical and professional responsibilities do not allow this.” Although it might have been possible, at the time the 2019 rule was promulgated, to predict that providers would withdraw, any such prediction would have been uncertain. That so many providers did in fact withdraw from the program is a change in circumstances that, in the Department’s view, demands reconsideration of the 2019 rule.

In addition to the grantees that withdrew from Title X completely, many other grantees that continued to receive Title X funding had subrecipients and service sites within their existing networks withdraw from the program. Overall, 19 grantees, including 231 subrecipients and 945 service sites, withdrew from the Title X program shortly after the rule took effect. Additionally, 18 grantees that continued in the program reported losses to their service network (*i.e.*, exiting subrecipients) because of the 2019 final rule. As a result, the Title X program provided services to 844,083 fewer clients in 2019 compared to 2018.³ Comparing Family Planning Annual Report (FPAR) data for 2018 and 2019, OPA estimates that 94% (or 789,960) of the total decrease (844,083) in clients can be attributed to the 2019 rule. A total of 41 states and two territories saw a decrease in clients served in 2019 compared to 2018. Of those, seven saw a decline of more than 40 percent in clients served (AK, HI, MD, UT, VT, WI, and WV), seven saw a decline of 31–40 percent (CA, CT, ME, MN, NH, NM, and NY), seven saw a decline of 21–30 percent (AZ, IL, MA, MT, NJ, OR, and WA), seven saw a decline of 11–20 percent (IA, IN, MI, OH, PA, VA, and the Marshall Islands), nine saw a decline of 5–10 percent (AL, AR, KY, NE, NC, ND, SC, TN, and WY), and six saw a decline of five percent or less (DE, CO, LA, OK, SD, and the U.S. Virgin Islands). Only nine states, six territories and the District of Columbia saw their number of clients served stay the same (FL, KS, MO, RI, and TX) between 2018 and 2019 ($\pm 1\%$) or increase (GA, ID, MS, NV, six territories, and DC), with the majority experiencing a small annual increase of between 70 to 3,000 clients. Minor fluctuations notwithstanding, 789,960 fewer clients were served, which had a disproportionate impact on minority

clients, adolescent clients, lower-income individuals, and those without insurance—all outcomes directly attributable to the 2019 rule. Most concerning, there are six states that formerly had Title X services that currently have no Title X services available (HI, ME, OR, UT, VT, and WA) and seven states with Title X services available on a very limited basis (AK, CT, IL, MA, MN, NH, and NY). The Department believes that these stark facts, which became clear only after the promulgation of the 2019 rule, justify reconsideration of that rule.

To ensure continuity of services and maintain a safe environment for clients and staff during the pandemic, Title X providers followed guidance issued by the Centers for Disease Control and Prevention (CDC), OPA, and others to manage supply and staffing shortages, and they implemented creative strategies tailored to their circumstances and clientele (virtual telehealth, for example). Despite these efforts, in 2020 vs. 2019, Title X had 193 fewer subrecipients (867 vs. 1,060) and 794 fewer service sites (3,031 vs. 3,825). The decrease in the size of the Title X service network appears to have substantially reduced the availability of and, consequently, access to Title X services. In 2020, Title X served 1.6 million fewer family planning users than in 2019 (1.5 million vs. 3.1 million), and Title X service sites delivered care to 302 fewer users per site (507 vs. 809). Furthermore, in 2020, Title X conducted almost 2.0 million fewer family planning encounters than in 2019 (2.7 million vs. 4.7 million). While the 2020 data undoubtedly reflect the public health emergency related to the COVID–19 pandemic, the pattern of the losses in the program initiated by the 2019 rule was exacerbated in 2020 for an already disrupted and weakened network.

Of additional concern, the 2019 rule has had a disproportionate impact on low-income clients, who are precisely the population that the Title X program was established to serve. The 2019 rule has significantly decreased the number of low-income, uninsured, and racial and ethnic minorities accessing Title X services. Following implementation of the 2019 rule, 573,650 fewer clients under 100 percent of the federal poverty level (FPL); 139,801 fewer clients between 101 percent FPL to 150 percent FPL; 65,735 fewer clients between 151 percent FPL and 200 percent FPL; and 30,194 fewer clients between 201 percent FPL to 250 percent FPL received Title X services. This contradicts the purpose and intent of the Title X program, which is to prioritize and

¹ Both circuit courts also differed on the permissibility of the rule under section 1554 of the Affordable Care Act.

² Withdrawn grantees included (1) Family Planning Association of Maine, Inc., (2) Hawaii Department of Health, (3) Health Imperatives, Inc. (MA), (4) Illinois Department of Health, (5) Maryland Department of Health, (6) Massachusetts Department of Public Health, (7) Oregon Health Authority, (8) Planned Parenthood Association of Utah, (9) Planned Parenthood Minnesota, North Dakota, South Dakota, (10 & 11) Planned Parenthood of Great Northwest & the Hawaiian Islands (two separate grants), (12) Planned Parenthood of Greater Ohio, (13) Planned Parenthood of Illinois, (14) Planned Parenthood of Northern New England, (15) Planned Parenthood of Southern New England, (16) Public Health Solutions (NY), (17) New York Department of Health, (18) Vermont Agency of Human Services, and (19) Washington State Department of Health.

³ (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from <https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf>.

increase family planning services to low-income clients. Additionally, 324,776 fewer uninsured clients were served in 2019 compared to 2018. FPAR data also demonstrate that in 2019 compared to 2018, 128,882 fewer Black or African Americans; 50,039 fewer Asians; 6,724 fewer American Indians/Alaska Natives; 7,218 fewer Native Hawaiians/Pacific Islanders; and 269,569 fewer Hispanics/Latinos received Title X services.⁴ Additionally, 151,375 fewer adolescent clients received essential family planning services in 2019. The Department believes these new facts warrant a reconsideration of the 2019 rule.

The mandate of the Title X program is to support access to critical family planning and preventive health services; unfortunately, the result of the 2019 rule ran counter to that effort. The 2019 rule undermined the mission of the Title X program by helping fewer individuals in planning and spacing births, providing fewer preventive health services, and delivering fewer screenings for sexually transmitted infections (STIs). More specifically, in 2019 compared to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008 fewer clients received intrauterine devices (IUDs). Additionally, 90,386 and 188,920 fewer Papanicolaou (Pap) tests and clinical breast exams, respectively, were performed in 2019 compared to 2018. Confidential human immunodeficiency virus (HIV) tests decreased by 276,109. STI testing decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis. Furthermore, 71,145 fewer individuals who were pregnant or sought pregnancy were served.⁵

In the 2019 rule, the Department stated that the rule was “expected to increase the number of entities interested in participating in Title X as grantees or subrecipient service providers and, thereby, to increase patient access to family planning services focused on optimal health outcomes for every Title X client.” 84 FR at 7782 (March 24, 2019). However, this expectation proved unwarranted. Despite several attempts, OPA has been unable to recruit new grantees and new providers into the Title X program to fill the current gaps in services resulting from implementation of the 2019 rule.

First, OPA issued competitive supplemental funding of \$33.7 million to 50 existing Title X grantees in fiscal year 2019 to expand their Title X services. Unfortunately, even with the additional funding, the majority of states were not able to increase the number of service sites in their Title X networks. From 2018 to 2020, 38 states and territories saw a decrease in the number of service sites in their networks, 12 saw no change in their number of service sites, and only nine saw an increase in the number of service sites. Analyzing users between 2018–2020 for those nine states that gained service sites, six still lost users (WV, AZ, DE, NE, CO, and TX) while three gained users (GA, NV, and Palau). Next, OPA issued a competitive funding announcement in fiscal year 2020 to recruit new grantees to provide Title X services in unserved or underserved states and communities. The number of applications received was so low (eight eligible applications received) that the resulting grant awards were for less than the total amount of funding available (grant awards for \$8.5 million with \$20 million available), and OPA was only able to fund grantees to provide services in three states with no or limited Title X services at the time.

The lack of organizations applying for Title X grant funding following implementation of the 2019 rule and the lack of new service sites willing to join existing Title X grantees as providers strongly suggest that the Department was wrong to believe that the 2019 rule would increase the number of grantees and providers. Rather, the 2019 rule appears to have had the opposite effect and resulted in a significant loss of grantees, subrecipients, and service sites, and close to one million fewer clients served from 2018 to 2019. The Department believes that this record warrants a change in course.

The decline in clients served and services provided is devastating. The Title X program is the only federal grant program dedicated to providing comprehensive family planning and related preventive health services. Title X clinics provide services to clients, with priority given to persons from low-income families. Title X services are voluntary, confidential, and provided regardless of one’s ability to pay. For many clients, Title X clinics are their only ongoing source of healthcare and health education. In fact, six in 10 women who go to a publicly funded

family planning clinic consider it their usual source of medical care.⁶

While some family planning providers that withdrew from the Title X program were able to continue providing reproductive health services at some level in the absence of Title X funding, the services provided were not the same as those provided under Title X. Grantees that relinquished their Title X funding at the time made clear that they were not able to provide the same breadth of services as they had been able to under Title X and were not able to provide services using the same schedule of discounts as required in the Title X program. According to several comments received, the loss of Title X funding meant that organizations had to adjust their fee schedules and push more costs for services to the clients. As a result, organizations saw more clients forgoing recommended tests, lab work, STI testing, clinical breast exams, and pap tests. Further, due to costs, organizations saw some family planning clients outside of the Title X network choose less effective methods of birth control.

The 2019 rule abandoned major portions of *Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the U.S. Office of Population Affairs* (QFP),⁷ such as nondirective options counseling and referrals, and the client-centered approach recommended by QFP, over the objection of every major medical organization and without any countervailing public health rationale. QFP recommendations support providers in delivering quality family planning services and define family planning services within a broad context of preventive services, to improve health outcomes for individuals and their (future) children. QFP recommendations are based on a rigorous, systematic, and transparent review of the evidence and were developed with input from a broad range of clinical experts, OPA, and the CDC. These recommendations not only improve the quality of care provided to family planning clients, but they foster a supportive and communicative relationship between provider and patient. As evident from grantee relinquishment letters and comments

⁶ Frost, J., Gold., Hasstedt, K., & Sonfield, A. (2014). *Moving Forward: Family Planning in the Era of Health Reform*. New York: Guttmacher Institute.

⁷ CDC. (2014). *Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs*. Accessed on March 8, 2021 from <https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning>.

⁴ (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from <https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf>.

⁵ (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from <https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf>.

received in response to the 2021 NPRM, abandoning major portions of this approach has damaged the patient-provider relationship. Moreover, the 2019 rule required prenatal referral even if the patient objected, an approach which also does not comport with well-accepted public health and clinical care principles.

On January 28, 2021, President Biden issued a “Memorandum on Protecting Women’s Health at Home and Abroad.”⁸ The Memorandum stated that “[w]omen should have access to the healthcare they need. For too many women today, both at home and abroad, that is not possible. Undue restrictions on the use of Federal funds have made it harder for women to obtain necessary healthcare. The Federal Government must take action to ensure that women at home and around the world are able to access complete medical information, including with respect to their reproductive health.” The Memorandum then instructed the Department to “review the Title X Rule and any other regulations governing the Title X program that impose undue restrictions on the use of Federal funds or women’s access to complete medical information and shall consider, as soon as practicable, whether to suspend, revise, or rescind, or publish for notice and comment proposed rules suspending, revising, or rescinding, those regulations, consistent with applicable law, including the Administrative Procedure Act.”

HHS reviewed the 2019 regulations pursuant to the President’s memorandum. Following this review, on April 15, 2021, the Department issued a Notice of Proposed Rulemaking (NPRM) for public comment (86 FR 19812, April 15, 2021), proposing rules to revise the 2019 regulation by essentially readopting the 2000 regulations. 65 FR 41270 (July 3, 2000). The 2000 regulations were consistent with applicable statutory commands, were widely accepted by grantees, enabled the Title X program to operate successfully, and led to no litigation over their permissibility.

Based on the evidence that has emerged since the adoption of the 2019 rule, as well as a fresh consideration of the evidence that existed at the time, the negative public health consequences of the 2019 rule are clear. The rule dramatically reduced access to family planning and preventive health services that are essential for hundreds of

thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to family planning services within states across the country and in rural and urban communities alike. The 2019 rule shifted the Title X program away from its history of providing client-centered quality family planning services and instead set limits on the patient-provider relationship and the information that could be provided to the patient by the provider. The 2019 rule resulted in increased costs for grantee reporting that are unnecessary for ensuring grantee compliance. Continued enforcement of the 2019 rule raises the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations and other disproportionately impacted communities, such as those in rural regions, minority clients, and adolescent clients, are relegated to inferior access. The populations served by Title X may already face health inequities driven by financial and access barriers to quality care that would be exacerbated by continuing to allow limited or delayed healthcare choices and biased or insufficient healthcare information. Given that so many individuals depend on the Title X program as their primary source of healthcare, the Department recognizes that this is a situation that must be rectified with urgency in the interest of public health and equity.

Most importantly, in readopting the 2000 rule, this final rule removes the strict physical separation requirements that were imposed on top of existing obligations for separation between abortion services and Title X project related activities. It also allows Title X providers to provide truly nondirective counseling and refer their patients for all services desired by the client, including abortion services. The 2000 regulations successfully governed the Title X program for decades and were widely accepted by grantees.

The 2019 rule imposed an interrelated set of requirements that are difficult to disentangle provision by provision. For example, 59.5(a)(5) prohibited funded projects from providing, promoting, referring, or supporting abortion as a method of family planning. Section 59.13 concurrently required assurance that a project did not “include abortion as a method of family planning” backed by documentary evidence of Subsections 59.14–59.16. The interrelatedness of these requirements

was underscored by 59.7(b) requiring applicants to “clearly address how the proposal will satisfy the requirements of the regulation,” before even proceeding to competitive consideration. Most of the 2019 provisions did not function independently of each other.

The Department did initially propose keeping portions of two provisions from the 2019 rule regarding compliance reporting (59.5(a)(12)) on state sexual abuse notification laws and subrecipient monitoring (59.5(a)(13)). As further explained below, these provisions created administrative costs for grantees and the government with no measurable benefits. These provisions, like the entire 2019 rule, depended on assumptions about how the program should work and grantee compliance even with no evidence of grantee non-compliance.

Given these considerations, the Department has determined that the most appropriate course is to revoke the 2019 rule in its totality. Every court to rule on the 2019 rule also believed that all of its provisions were of a piece and either struck down or upheld the rule in its entirety. See, e.g., *Mayor of Baltimore v. Azar*, 973 F3d 258, 292 (4th Cir. 2020) (“Despite the severability clause, the Final Rule is not severable because it is clear HHS ‘intended the [Final Rule] to stand or fall as a whole,’ and the agency desired ‘a single, coherent policy, the predominant purpose of which’ is to reinstitute the 1988 Rule.”).

As compared to the 2019 rule, new provisions added to the re-adoption of the 2000 rule operate independently of each other—and the 2000 rule—to enhance the program. Particularly as the program operated for decades under the 2000 rule, the 2021 additions are severable from the 2000 rule. For example, while adding to the statutory goals of reaching low-income and underserved individuals, if the added grant evaluation criteria of equity, 59.7(a)(3), was excised, the program could still accomplish its mission successfully using the 2000 criteria alone. And, were a court to strike down the new income verification measures in 59.5(a)(9), the program would be able to accomplish its mission using the 2000 criteria alone.

In addition to readopting the requirements as they existed prior to the 2019 rule, the 2021 rule also includes several revisions that will strengthen the Title X program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients, while retaining the longstanding prohibition on directly promoting or performing abortion that follows from

⁸ Available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/28/memorandum-on-protecting-womens-health-at-home-and-abroad/>.

Section 1008's text and subsequent appropriations enactments.

Advancing equity for all, including people from low-income families, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for the Department, for OPA, and for the Title X program. By focusing on advancing equity in the Title X program, we can create opportunities to support communities that have been historically underserved, which benefits everyone. The 2021 rule was written to ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access. Key strategies for advancing equity include removing barriers to accessing services, improving the quality of services, and providing services that are client-centered. Several revisions in the rule focus on improving access to services. These revisions include clearly defining what constitutes a broad range of acceptable and effective family planning methods and services, requiring service sites not offering a broad range of methods on-site to provide a prescription to the client for their method of choice or referrals, as requested, clarifying required billing practices and income verification for low-income clients, enabling a broader range of clinical services providers to direct Title X services and to provide consultation for medical services, and strengthening client confidentiality.

Several revisions in the 2021 rule focus on improving quality of Title X services. These revisions include clearly defining quality healthcare as safe, effective, client-centered, timely, efficient, and equitable; incorporating QFP's definition of family planning into the regulation; and requiring all family planning services to be delivered consistent with nationally recognized standards of care. Finally, several revisions in the 2021 rule focus on ensuring client-centered care. These revisions include clearly defining client-centered care as being respectful of, and responsive to, individual client preferences, needs, and values and where client values guide all clinical decisions, and requiring all family planning services to be client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed.

II. Public Comment and Departmental Response

The Department provided a 30-day public comment period for the proposed rule. That period closed on May 17, 2021. A total of 180,266 public comments were submitted to www.Regulations.gov or directly to the Department.

With this 2021 final rule, the Department revokes the requirements of the 2019 regulations (84 FR 7714, March 24, 2019) and readopts the 2000 regulations (65 FR 41270, July 3, 2000) with several revisions. In the section below, the Department discusses the public comments, its responses, and the text of the final rules. The Department first presents a summary of public comments received related to revoking the 2019 regulation and readopting the 2000 regulation. The Department then provides a summary of comments received regarding the revisions and technical corrections proposed in the NPRM to specific provisions of the 2000 regulations. The NPRM proposed 14 revisions, including to 59.2, 59.5(a)(1), 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(a)(12), 59.5(a)(13), 59.5(b)(1), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, 59.10, and 59.11. The NPRM also proposed 10 technical corrections, including to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), 59.8, and 59.12. The Department received comments on all the revisions proposed in the NPRM and three of the 10 technical corrections. The Department did not receive comments on the revision to 59.11, nor to the technical corrections to 59.2, 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(2), 59.5(b)(3), or 59.8. A summary of comments and the Department's response are only provided for those revisions and technical corrections that received comments. In addition, the Department received public comments requesting a revision to 59.5(b)(6) that was not proposed in the NPRM, but that is related to the revision that was proposed in the NPRM to 59.5(b)(1). A summary of these comments and the Department's response are also included below.

After considering the comments, the Department adopts the regulations proposed for public comment on April 15, 2021 at 86 FR 19812 with nine additional revisions and six additional technical corrections to what was proposed in the NPRM.

General Comments Related To Revoking 2019 Regulations and Readopting the 2000 Regulations

A. Compliance With Section 1008 (42 U.S.C. 300a-6)

Comments: Thousands of comments expressed concern that the program's returning to the 2000 regulations violated both the Title X statute and the Court's holding in *Rust v. Sullivan*, 500 U.S. 173 (1991). Many comments stated referral for abortion "squarely" violated the "plain" "clear" text of section 1008. Many of these same comments also asserted the statute requires separation from abortion activities because they are programs "where" abortion is a method of family planning. Both comments believing the 2000 rule to be unlawful, and those affirming it to be lawful, cited *Rust* as well as legislative history in making their arguments.

Those opposing the proposed rule also stressed that private organizations have no right to federal funding, much less to federal funding to perform abortions. These comments stated that "[m]oney is fungible," and reverting to the 2000 rule will create so-called "slush funds" and infrastructure for organizations to perform abortions in violation of section 1008. They also suggested that the 2000 rule lacked any mechanism to ensure compliance with the statute, and that the NPRM, in fact, violates the statute because the proposed definition of "family planning" includes related "pregnancy counseling" which requires referral for abortion when requested (59.5(a)(5)). Many comments asserted that revoking the 2019 rule would allow grantees to engage in lobbying and other activities encouraging abortion that violate section 1008.

Response: As stated in the NPRM, the Supreme Court held in *Rust*: "[W]e agree with every court to have addressed the issue that the language is ambiguous. The language of § 1008—that 'none of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity." *Rust* at 184. No court adjudicating the 2019 rule found that the separation, referral, or other requirements were required by *Rust*. Such a finding would be contrary to the primary holding in *Rust*. Counseling for abortion, including referral when requested, has never been held to constitute a violation of section 1008.

Interpreting section 1008 to prohibit referrals and require strict separation would also be inconsistent with nearly

40 years of agency practice under the program across numerous administrations. Such an interpretation would also appear contrary to decades of close Congressional oversight, including annual Title X appropriations riders, and a specific annual line item appropriation through which Congress can be—and has been—quite clear as to how the agency should operate.

In readopting the 2000 rule, the program is also reinstating interpretations and policies under section 1008 of the statute that were in place for much of the program's history and published in the **Federal Register** in 2000. 65 FR 41281 (July 3, 2000). Those program policies discuss, for example, the requirements for separation: "Separation of Title X from abortion activities does not require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008." 65 FR at 41282 (July 3, 2000). Also, "[w]hile a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient." 65 FR at 41281 (July 3, 2000). Finally, while a Title X project may not advocate for abortion as a method of family planning, it "may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project)." *Id.* Interested entities are encouraged to consult this notice.

The Department agrees that it is not under a duty to subsidize abortion. It does not do so, and it is prohibited from doing so. As discussed in the NPRM, legislative history and longstanding appropriations riders prohibit Title X funds from being expended on abortion. See, e.g., Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 207, 134 Stat. 1182, 1590. More generally, Section 507 of the Consolidated Appropriations Act, 2021 prohibits federal funds from being used for abortion except for cases of rape, incest, or maternal health. *Id.* at sec. 507. As discussed in the NPRM and

above, the Department employs a variety of mechanisms to enforce such restrictions, such as regular grant reports, compliance monitoring visits, third-party audits, compliance guidance, and grantee education. None of these oversight tools have uncovered any more than minimal problems with grantee compliance under section 1008.

The Department also agrees that no particular private organizations have a right to Title X funding. The program is returning to the program requirements in operation for the majority of its history because those requirements best serve individual clients and the public health. In the wake of the 2019 rule, both private organizations and states withdrew from the program, leaving multiple states without any Title X providers and the agency struggling to meet its mandate to provide family planning services for low-income populations in areas of high need. Though in some places organizations and jurisdictions were able to temporarily provide resources to replace the loss of Title X funds, providers were not always able to provide the same scope of services or seamless care coordination that Title X projects can provide. Public comments from those organizations made clear that they were not able to provide the same breadth of services, nor were they able to provide services with the same schedule of discounts for low-income clients.

The Department disagrees that Title X grant funds allow for the "creation of slush funds" or that those funds are "fungible." As stated above, the Department has multiple methods by which it confirms that grant funds are spent for grant purposes, and it has concluded that grantees comply, not just with section 1008, but with Congressional directives and other requirements of the program. Again, the 2019 rule could point to no significant compliance issues related to the diversion of Title X grant funds, and a fresh review of decades of evidence has uncovered no such issues. A ban on organizations receiving Title X funds for lawful activities outside of the Title X project would go beyond the 2019 rule and raise serious constitutional issues. And even if such a restriction might conceivably be lawful, the Department clearly has the discretion to open eligibility to the most qualified Title X providers.⁹

⁹ Zolna, M.R., & Frost, J.J. (2017, August 2). *Publicly funded family planning clinics in 2015: Patterns and trends in service delivery practices and protocols*. Guttmacher Institute. Retrieved from <https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015>.

B. Data on Negative Public Health Consequences of 2019 Rule

Comments: A few comments took issue with data presented in the NPRM. They stated that the Department used flawed data and failed to account for the effects of COVID–19, instead attributing the loss of grantees and subrecipients and the decline in services to the 2019 rule. One comment stated that the Department does not have data to assess the effect of the 2019 rule. Another comment argued that the decline in clients served is the result of a long time decline since the 2000 rule. One of those same comments reflected the belief that the decline in services is instead related to changes in insurance, changes in poverty, and use of the most effective contraceptive methods, and that declines have been continuous since 2000.

Some of the comments also took issue with the Department's position that the withdrawal of grantees from the program in response to the 2019 rule resulted in a decline in services, as they stated those services were continued with state and private funds and not discontinued, and the Department's claims of fewer services provided is "a red herring." The same comment pointed out the proposed rule noted that seven states saw an increase in clients after the 2019 rule. Another comment cited Planned Parenthood data showing that Planned Parenthood provided more services in 2020 compared to 2019 and that other providers stepped in to fill the gaps in services left when Planned Parenthood exited the Title X program. It cited Ohio as an example and said that additional clients would be served post-COVID–19. A final opposing comment claimed that the number of new providers applying for Title X funds increased after the publication of the 2019 rule.

In contrast, numerous comments supported the 2021 NPRM and shared data on the negative impact that the 2019 rule has had in their states and communities, reinforcing the Department's statements in the NPRM. Many of the comments spoke to the drastic reduction in clients they were able to serve after the 2019 regulation. One comment stated, "throughout the history of Title X, since its inception in 1970, there has never been as sharp a decline in the number of patients served by the program as occurred between 2018 and 2019." More than losing numbers of clients, numerous comments spoke to the types of clients they have not been able to serve and the nature of services that are being lost because clients cannot afford those services.

Several comments noted that the 2019 regulation is disproportionately impacting rural regions, minority clients, adolescent clients, lower-income individuals, and those without insurance, particularly in states that have not expanded Medicaid.

Contrary to the comments that expressed Planned Parenthood affiliates were able to provide more services after leaving the Title X program, Planned Parenthood affiliates themselves, in addition to other commenters, indicated that without Title X funding, they have had to adjust their sliding fee scales, pushing more costs onto the clients. Comments stated that this has resulted in clients forgoing recommended tests, lab work, STI testing, clinical breast exams, and Pap tests in large numbers. Further, these comments provided evidence that some clients are choosing less effective methods of birth control due to costs. Other comments stated that the changes in fees have pushed their clients into seeking care elsewhere, interrupting their continuity of care. One comment reported that the loss of Title X funding resulted in loss of eligibility for the 340B Drug Pricing Program, requiring the agency to dispose of contraceptive methods purchased under the 340B Program and repurchasing them at higher market prices.

The Attorneys General of 22 states and the District of Columbia commented that the emergency, one-time,¹⁰ and private funding made available to replace the loss of Title X funding has strained state budgets and could not be sustained, creating uncertainty for the future of their family planning providers. Additionally, several comments noted that the fundraising activities necessitated after leaving the Title X program have come at a cost and have resulted in providers having to scale back or eliminate educational and outreach programs in many states. Other comments noted that it was extremely burdensome to try to identify and recruit additional providers to fill the gaps left after the 2019 rule. Many commenters expressed strong interest in rejoining the Title X network once the current rule is replaced. Finally, several states reported that while their efforts were refocused on recruiting and onboarding new providers into their Title X network under the 2019 rule, they faced much resistance and/or a lack of interest, and their provider networks did not increase under this

rule, continuing to adversely impact the communities they serve.

Response: The Department believes that the negative public health consequences of the 2019 rule are clear. The rule dramatically reduced access to essential family planning and related preventive health services for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to essential family planning services within states and communities across the country.

The Department disagrees that the data cannot distinguish between enactment of the 2019 rule and the pandemic. The 2019 rule officially took effect mid-year in 2019, but COVID-19 was not announced as a national emergency until early 2020. The Department has data to assess the impact of the 2019 rule through FPAR and grantee progress reports, including data on the decrease in the number of clients served in 2019 when the rule was in place and prior to COVID-19. As stated in the Background section, 19 grantees, 231 subrecipients, and 945 service sites immediately withdrew from the Title X program. As a result, the Title X program provided services to 844,083 fewer clients in 2019 compared to 2018, prior to the implementation of the 2019 rule, approximately a 22 percent decrease. A total of 41 states and two territories saw a decrease in clients served in 2019 compared to 2018; five states saw their number of clients served stay the same; and four states, five territories, and the District of Columbia saw an increase in clients served from 2018 to 2019, with the majority experiencing a small annual increase of between 70 to 3,000 clients. Minor fluctuations notwithstanding, 844,083 fewer clients were served, disproportionately impacting lower-income individuals, minority clients, adolescent clients, and those without insurance. There are currently six states with no Title X services available and seven states with Title X services available on a very limited basis. Ultimately, the hundreds of thousands of clients who lost access to Title X services as a result of the 2019 rule lost access to critical family planning and preventive health services. As noted in the background, this included declines in contraceptive services, Pap tests, clinical breast exams, and HIV and STI testing.

The Department agrees that a few states were able to increase their service sites following the 2019 rule, but these

are the exception. From 2018 to 2020, 34 states and territories saw a decrease in the number of service sites in their network, 18 saw no real change in their number of service sites, and only seven saw an increase in the number of service sites. OPA attempted to recruit new grantees to provide Title X services through a competitive funding opportunity, but OPA only received eight applications and was only able to provide services in three of the states with no or limited Title X services at the time. Some comments opposing the 2021 NPRM specifically cited Ohio as an example of a state that would be able to increase clients served post-COVID-19. Despite the state health department receiving additional funds to provide Title X services following the departure of another grantee, FPAR data from Ohio, however, do not provide any clear support for this claim and reinforce that capacity among entities is not necessarily equivalent. According to the FPAR data from Ohio, the state experienced a 10 percent decline in service sites between 2018 and 2020, an 18 percent decline in clients from 2018 to 2019, and a 57 percent decline in clients from 2019 to 2020. While many states and territories experienced a decline in clients from 2019 to 2020 due to COVID-19, Ohio's percentage decline in clients from 2019 to 2020 ranked 18th in order of states from largest decline to smallest decline. Seventeen states experienced a larger decline in clients from 2019 to 2020, and 41 states and territories experienced a smaller decline in clients. The data show that even if the same amount of funding is provided to a different set of grantees in a given area, it does not necessarily follow that the same number of clients will be served or same number of services will be provided, depending on the differences in grantee service capacity. Existing Title X grantees also experienced great difficulty recruiting new sites and new providers into their existing Title X networks under the 2019 regulations, as evidenced by the lack of states experiencing an increase in their number of service sites. Overall, it is clear that the 2019 rule directly resulted in a significant loss of grantees, subrecipients, and service sites, and close to one million fewer clients served from 2018 to 2019.

While some states and organizations were able to provide family planning and related preventive health services in the absence of Title X funding, the comments made clear that they were not providing the full scope of services provided under the Title X program, they were not provided following the

¹⁰ States that provided emergency funding include CA, MA, MD, NY, OR, WA, and VT.

same standards as in Title X, and the same schedule of discounts and subsidies were not applied as required in the Title X program. Finally, many of the states that provided emergency or one-time funds, or those organizations that were able to raise funds privately, indicated through their comments that they could only do so on a very short-term basis, that it was not sustainable for the long term, and that it came at a price—requiring elimination of other critical services.

Given the data presented in the preamble and the data presented above, the Department disagrees with the claim that Title X services would improve after COVID-19 (absent a change in the 2019 rule). The loss in clients served, the states with no service providers, and the states with limited service providers occurred in 2019 after enactment of the 2019 rule and prior to COVID-19, making it unlikely that the number of clients served or services provided would increase to pre-2019 levels or above without a change to the 2019 rule. Comparing FPAR data for 2018 (“typical year”) and 2019 (post 2019 rule but pre-COVID), OPA estimates that 94% (789,960) of the total decrease (844,083) in family planning clients between 2019 and 2020 can be attributed to the 2019 rule. Further comparing FPAR data for 2018 (“typical year”) and 2020 (post-COVID), OPA estimates that 63% (or 1.5 million) of the total decrease (2.4 million) in family planning users between 2018 and 2020 can be attributed to the final rule. The grantees and subrecipients that left the program have indicated that they will not return to the program under the 2019 rule. Coupled with the lack of additional applicants to the Department’s funding opportunity, the Department maintains the decline in access, clients, and services from 2018 levels will continue until a new rule is in place.

C. Grantee and Subrecipient Compliance

Comments: Several comments expressed concern that the 2021 NPRM did not include language from 59.1 in the 2019 rule, stating, “the requirements imposed by these regulations apply equally to grantees and subrecipients.” Several comments also expressed concern that the 2021 NPRM did not include language from 59.13 specifically requiring grantees to provide assurance that their project does not provide abortion and does not include abortion as a method of family planning. One comment stated that “[t]he removal of an explicit compliance requirement, without at minimum an explanation that subrecipients are assumed to have

to comply with all Title X regulations, suggests that such compliance is no longer required.”

Another comment claimed that the departure of providers from the Title X network after the introduction of the 2019 rule confirmed that Title X funding had been used by those providers for impermissible purposes. Additionally, the comment claimed that the withdrawal demonstrates an unwillingness to comply with program requirements, and that “healthcare providers were accepting Title X funding for years without complying with the statutory requirements of the program.”

Response: The Department disagrees with the comments and does not believe that it is necessary to include language within the Title X regulations stating that the regulations apply equally to grantees and subrecipients because this is already a requirement in the HHS grants regulations that apply to Title X grantees. All Title X grantees are subject to 45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. In fact, Title X Notices of Funding Opportunity (NOFOs) state that successful applicants that accept an award agree that the award and all activities under the award are subject to all provisions of 45 CFR part 75. Specifically, 45 CFR 75.352 sets out the requirements for pass-through entities and clearly specifies that “all pass-through entities must (a) ensure that every subaward is clearly identified to the subrecipient as a subaward and includes the following information at the time of the subaward and if any of these data elements change, include the changes in subsequent subaward modification. . . . Required information includes . . . (2) All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award.” Given that Title X grantees are required to follow 45 CFR part 75, and since 45 CFR part 75 makes clear that all requirements of the grant, including federal statutes, regulations, and terms and conditions of the federal award, apply to all subrecipients, the Department believes it is clear that the Title X regulations will continue to apply equally to all grantees and subrecipients without needing to include separate language in the Title X regulations.

Similarly, the Department does not deem it necessary to include language within the regulation itself requiring

grantees to provide assurance that their project does not provide abortion and does not include abortion as a method of family planning. The Department has explicitly stated in all NOFOs that all grantees must comply with the Title X statute, regulations, and legislative mandates, and applicants certify in the application materials that they “[w]ill comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.” Additionally, compliance with program statutes and appropriations act requirements is included as a standard term of the grant award. Therefore, during the application process, and by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates.

The Department also disagrees with the contention that withdrawal of organizations following the 2019 rule proves that these organizations were non-compliant with the statutory requirements. The primary reasons cited by most grantees for withdrawing from the Title X program after promulgation of the 2019 rule was out of concern that the 2019 rule interfered with the patient-provider relationship and compromised their ability to provide quality healthcare to all clients. For certain grantees, the regulation was also in direct conflict with laws established by their state.

Furthermore, there is no evidence to suggest that the grantees that withdrew from the Title X program had had any difficulties complying with the Title X statute, regulations, or legislative mandates. OPA practices, and practiced long before the 2019 rule, robust monitoring processes to ensure grantee compliance with the statute and regulations, including through regular grant reports, compliance monitoring visits, and legally required audits. As stated in the Background section, close oversight of Title X grantees for almost two decades under the 2000 rule uncovered no misallocation of Title X funds by grantees. OPA oversight did identify occasional instances over the years where grantees needed to update their written policies to clearly reflect the Title X statutory language, but OPA never found any instance where grantees were co-mingling funds with activities not allowed under the statute. The Department believes that grantee compliance with the Title X statute and regulations has not been an issue throughout the history of the Title X program, and the compliance monitoring methods that have historically been applied by OPA prior to the 2019 rule have ensured that

grantees have an understanding of the statute and how to comply with it. The Department rejects as without merit the comments that these grantees were accepting Title X funding for years without complying with statutory requirements. Neither the 2019 rule itself nor any comments to the 2021 NPRM cited evidence of widespread noncompliance.

D. Application of Conscience and Religious Freedom Statutes to Title X

Comments: The Department received thousands of comments on the preamble language concerning the application of the conscience statutes to Title X. As further discussed in the NPRM, Congress has passed several laws protecting the conscience rights of providers, particularly in the area of abortion. For instance, under 42 U.S.C. 300a–7, the Church amendments, grantees may not require individual employees who have objections to abortion to provide such abortion counseling, or those who have objections to sterilization procedures to perform, assist in the performance of, or provide counseling regarding sterilizations. Since 2005, Congress has also annually enacted an appropriations rider, the Weldon amendment, which extends non-discrimination protections to other “health care entities” who refuse to counsel or refer for abortion. See, e.g., Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, section 507(d) (2020). Under these statutes, objecting providers or Title X grantees are not required to counsel or refer for abortions.

Many commenters expressed a belief that the statutory conscience protections prohibited the agency from promulgating any counseling or referral requirements. Conversely, some asserted that the conscience statutes have no bearing on what requirements Title X could impose on grantees by regulation. Many comments asserted that these statutes had to be incorporated into the Title X regulatory text for them to be operative or the rule to be lawful. Some stated that the statutes themselves violated the separation between church and state. Several other comments cited a concern that applications from providers objecting to abortion counseling or referral would not be favorably evaluated. Many also suggested that the Department should simply allow for abortion counseling and referral rather than requiring it, since the conscience statutes protect objecting providers from those requirements in any case.

Beyond the Church and Weldon Amendments, a few comments also

stated that requiring abortion counseling or referral automatically violated the Religious Freedom Restoration Act (RFRA), 42 U.S.C. 2000bb through 42 U.S.C. 2000bb–4. At least one comment suggested that the counseling and referral requirements coerced speech in violation of the First Amendment for those providers who object.

Response: The conscience statutes have been the subject of multiple rulemakings and numerous lawsuits in the last 13 years. Most recently, the Department finalized a rule in 2019 providing definitions and an enforcement mechanism for several statutes protecting medical providers who have conscience-based objections to certain activities. *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 FR 23170 (May 21, 2019). That rule was vacated by three different courts. *New York v. HHS*, 414 F. Supp. 3d 475, 536 (S.D.N.Y. 2019) (appeal in abeyance); *Washington v. Azar*, 426 F. Supp. 3d 704, 722 (W.D. Wash. 2019) (same); *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019) (same). While the statutes may at times interact with the requirements of Title X, interpreting these laws is beyond the scope of this rule and the HHS Office for Civil Rights (OCR) has been delegated authority to receive complaints under these provisions.

Moreover, as the DC Circuit pointed out when the Weldon Amendment was enacted and the 2000 Title X rule was in effect, “a valid statute always prevails over a conflicting regulation,” *Nat’l Family Planning & Reprod. Health Ass’n v. Gonzales*, 468 F.3d 826 (D.C. Cir. 2006). This is true whether an overriding statute is incorporated into regulatory text or not. The applicability of other rules and laws are best evaluated by consulting those rules and laws and then seeking guidance from the agencies responsible for implementing them. Particularly in areas where the administrative rules may be modified or statutory directions may change from appropriation to appropriation, it is unwise for OPA to formalize interpretations beyond its own statutory authority.

Irrespective of the points made above, as recounted in the NPRM, objecting individuals and grantees will not be required to counsel or refer for abortions in the Title X program in accordance with applicable federal law. OPA has long worked with grantees and providers to ensure appropriate compliance with conscience laws as well as continuity of care. As stated above, OCR has been delegated authority to receive any complaints

related to the conscience protections and will continue to enforce them. As discussed in the NPRM, recognition of provider conscience rights has been the position of the Department since before the 2000 rule. See 65 FR at 41274 (2000 rule, stating that under “42 U.S.C. 300a–(d), “grantees may not require individual employees who have such objections to provide such counseling.”). However, as also discussed in the 2000 final rule, the Secretary was unaware then—and is still unaware—“of any current grantees that object to the requirement for nondirective options counseling.” *Id.*

Just as non-objecting providers should not dictate the provision of information and referrals by those who do object, the existence of statutory conscience protections for providers does not preclude other willing providers from providing referrals or counseling for abortion within the program. With this final rule, the Department is emphasizing the importance of ensuring access to equitable, affordable, client-centered, quality family planning services. Client-centered care is defined as being respectful of, and responsive to, individual client preferences, needs, and values, and ensures that the client’s values guide all clinical decisions. With an emphasis on providing services that are client-centered, the default should be the fullest provision of information to clients. Providers may avail themselves of existing conscience protections and file complaints with OCR, which will be evaluated on a case-by-case basis as is done with other complaints.

As noted in previous iterations of both sets of rules, the conscience provisions and Title X rules have existed side by side for decades with very little conflict, or even interaction. From 1993 to 2017, Title X received no reports of grantees or individuals objecting to the regulatory requirement to counsel or refer for abortions when requested. See *Nat’l Family Planning & Reprod. Health Ass’n*, 468 F.3d at 830 (“[T]here are structural reasons to doubt that the issue will ever come up. In 2000 HHS Secretary Shalala declined to create a specific exception from the pending [Title X] regulation’s mandatory referral requirement for organizations resisting provision of abortion counseling or referrals; she explained that she was “unaware of any current grantees that object to the requirement for nondirective options counseling, so this suggestion appears to be based on more of a hypothetical than an actual concern.”). As with any issue facing Title X grantees and applicants, the program will work to provide guidance to grantees and coordinate any

conflicts with the OCR. A case-by-case approach to investigations will best enable the Department to deal with any perceived conflicts within fact-specific situations.

The Department declines to definitively interpret RFRA or the First Amendment in this context for largely the same reasons. Not only do the conscience protections more specifically allow providers to object to referral and counseling for abortion requirements, but the Title X rules in force for decades prior to the 2019 rule also existed side by side with RFRA and the First Amendment with no conflict. However, in light of the comments received, and to eliminate any confusion, the Department has noted in this final regulation that “[p]roviders may separately be covered by federal statutes protecting conscience and/or civil rights.”

E. Options Counseling

Comments: The Department received thousands of comments expressing support for “the reinstatement of the requirement to offer nondirective options counseling to pregnant patients.” Many comments expressed support for reversing the 2019 rule’s restrictions on what referrals can be provided to clients and allowing providers to offer patients complete information about their healthcare options and refer patients to providers who offer services to meet those needs. One comment stated that “reinstating the 2000 regulations would remove this undue governmental interference into medical care and will help ensure patients receive medically accurate, comprehensive information from their physicians.”

The Department also received comments in opposition to removing restrictions on referring for abortion services and requiring nondirective counseling. Several comments opposed removing restrictions on what referrals can be provided to clients in general, and a few opposed removing restrictions which state that only advanced practice providers can provide nondirective counseling. Many comments opposing the rule expressed a belief that the information and counseling requirements in this provision violate section 1008 of the Title X statute. Others believed that requiring “that grantees refer (sic) individuals to abortion providers conflicts with the free speech and religious freedom of grantees.” Still others expressed concern that the requirement could limit the type of providers in the program due to conscience concerns.

Response: The Department appreciates the comments in support of this provision. The Department believes that offering pregnant clients the opportunity to receive neutral, factual information and nondirective counseling on all pregnancy options—and providing referral upon request for option(s) the client wishes to receive—are critical for the delivery of quality, client-centered care. The Department agrees that restoring this provision will remove unnecessary limitations governing the patient-provider relationship and will enable healthcare providers to offer complete and medically accurate information and counseling to their clients.

The Department’s response to comments opposing this provision is included earlier in Section II. A. *Compliance with Section 1008 (42 U.S.C. 300a–6) and D. Application of Conscience Statutes to Title X.* The NPRM language for this provision would restore the regulatory text from the 2000 regulation, which successfully governed the Title X program for decades without opposition from major medical organizations and was widely accepted by grantees.

F. Subrecipient Nondiscrimination

Comments: The Department received many comments on state policies restricting subrecipient participation for reasons unrelated to the provider’s ability to provide care. The majority of these comments favored a regulatory prohibition on such restrictions because they often exclude the best family planning providers for no discernible purpose. Many comments stated that “State policies putting restrictions on how state funds are allocated, called ‘tiering,’ make it difficult or impossible for privately operated reproductive health-focused providers to receive funding. Tiering and other prohibitions against abortion providers often exclude the specialist providers that are the most qualified and best equipped to help Title X patients achieve their family planning goals.” Such restrictions, which are in place in approximately 15 states, can make access for certain subpopulations and geographic areas more difficult. Many comments stressed that “expelling well-qualified, trusted family planning providers from publicly funded health programs like Title X has adverse effects on patients’ access to critical family planning and sexual healthcare.”

The Department also received many comments, including from multiple state Attorneys General, condemning any regulation in this area. Many of these objections stated that such a

regulation would undermine federalism and “intrude on the States’ self-governance for no good reason,” and, most prominently, violate the Congressional Review Act, 5 U.S.C. 801–808. Under that law, an agency may not promulgate a rule that is “substantially the same” as one that has been disapproved by Congress. In 2016, the Department enacted a rule barring projects from rejecting sub-grantees for non-programmatic reasons. 81 FR 91852 (Dec. 19, 2016). Congress subsequently revoked the rule. P.L. 115–23 (4/13/2017). Multiple comments asserted that any regulation in this area would be unlawful unless Congress specifically authorized it.

Response: All proposed additions to the 2000 rule received an overwhelmingly positive response, except the proposal to include a subrecipient non-discrimination provision. After carefully considering several factors, the agency is declining to include a subrecipient non-discrimination provision in this rulemaking. Foremost among the Department’s considerations is the sense of urgency in the interest of public health to complete this rulemaking. This schedule allows for a final rule to be effective before the award of the next round of competitive funding for the Title X program. This, in turn, will enable applicants that previously withdrew from participation in the program as a result of the previous regulation to apply for funding.

The Department still believes state restrictions on subrecipients unrelated to care hamper the ability of the program to achieve its goals. However, the overriding task of this rulemaking is to undo the negative public health effects of the previous rule. That result is most effectively reached by not including a subrecipient non-discrimination provision in this rulemaking. Organizations in states with restrictive laws may still apply directly to receive Title X grants (*see* PHS Act sec. 1001(b); 59.3).

G. Other Comments

Comments: While many comments were specific to certain sections of the proposed rule, a sizeable number were more general in nature, or commented on portions of the preamble. Many of these general comments were summarized in detail in the sections above, and the remainder of the general comments are summarized here.

Of those that support the proposed rule, a large number of comments expressed general support for removing the harmful effects of the 2019 rule on Title X services. A similarly large

number felt that the 2019 rule negatively impacted the number of clients served and that the proposed rule will increase the number of clients served. Many comments supported being able to expand access to Title X services across the nation and within states and territories. They felt that the proposed rule will result in more Title X grantees and service sites and will increase the diversity of grantees. Many other comments expressed support that the proposed rule will increase health equity and decrease health disparities by increasing the number of marginalized and vulnerable groups served by Title X.

Many comments expressed a belief that the proposed rule will result in improved health outcomes and that the 2019 rule had a negative impact on public health. Others supported the emphasis in the proposed rule on quality family planning and felt that the proposed rule will result in improved quality of care. Many comments expressed a belief that the proposed rule better aligns with the mission of Title X and that it will result in cost savings.

Of those that oppose the proposed rule, many expressed general opposition to the elimination of the 2019 rule, and a large number expressed a belief that the proposed rule does not align with the mission of Title X. Several comments expressed a belief that the proposed rule will result in negative health outcomes. A small number of comments raised concern that the proposed rule will result in a decrease in quality of care and would cost more to implement compared to the 2019 rule.

The Department also received several comments that were not relevant to the 2021 rule. These included several comments expressing opposition to the use of hormone therapy for adolescents, a few comments requesting that the Department include specific services within Title X that are already included in Title X (e.g., STI testing, cervical cancer prevention and treatment), and several personal testimonials either for or against family planning in general, but not specific to the 2021 rule.

Response: The Department agrees with the comments in support of the proposed rule and disagrees with the comments opposed to the proposed rule. The Department believes that the negative public health consequences of the 2019 rule are clear. As stated in the Background section, the 2019 rule dramatically reduced access to essential family planning and preventive health services for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created

to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to essential family planning services within states and communities across the country. The 2019 rule shifted Title X away from its history of providing client-centered, quality family planning services and instead set limits on the patient-provider relationship and the information that could be provided to the patient by the provider. The 2019 rule resulted in increased costs for grantee reporting that are unnecessary for ensuring grantee compliance. The Department believes that continued enforcement of the 2019 rule raises the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations with fewer opportunities for care are relegated to inferior access.

The Department will continue to enforce and monitor grantee compliance with all Title X statutory requirements and legislative mandates. The Department disagrees with comments that it is necessary to include language repeating the legislative mandates within the regulation itself. As noted above with respect to Section II. C. *Grantee and Subrecipient Compliance*, OPA explicitly states in NOFOs that all grantees must comply with the Title X statute, regulations, and legislative mandates, and applicants certify in the application materials that they will comply with federal law; compliance with program statutes and appropriations act requirements is also included as a standard term of the Title X grant award. Therefore, during the application process as well as by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates. Furthermore, OPA includes the legislative mandates in its grantee orientation and trainings and regularly monitors grantee compliance with the legislative mandates through grantee reporting and compliance monitoring visits.

The Department believes that the adoption of the 2021 proposed rule (86 FR 19812, April 15, 2021), with minor modifications discussed in this rule, will result in increased access to equitable, affordable, client-centered, quality family planning services. This will result in improved outcomes for all clients served by Title X. Additionally, the 2021 rule will ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to

the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access.

Comments Regarding Proposed Revisions and Technical Corrections to the 2000 Regulation

§ 59.2. Definitions

In the NPRM, the Department proposed revising section 59.2 of the 2000 regulations by adding several new and modified definitions. The NPRM included a new definition of family planning services consistent with the definition included in QFP. The NPRM also included a new definition of service site consistent with the previous Title X Family Planning Guidelines that implemented the 2000 regulations, the 2014 *Program Requirements for Title X Funded Family Planning Projects* (“2014 Title X Program Requirements”). Finally, the NPRM included new definitions for adolescent-friendly health services, client-centered care, culturally and linguistically appropriate services, health equity, inclusivity, quality healthcare, and trauma-informed services. All new definitions included in the NPRM were taken from federal government agencies or major medical associations. The NPRM also retained definitions from the 2000 regulation for the following terms: Act, family, low-income, non-profit, Secretary, and state.

Comments: The Department received numerous comments in support of the new or revised definitions in the NPRM. Many comments expressed strong general support for the newly-proposed definitions, including definitions for client-centered care, cultural and linguistic appropriateness, family planning services, health equity, inclusivity, and trauma-informed. Numerous comments stated that “the proposed rule’s definitions help to illustrate key aspects of quality care” and that “defining how services should be provided is an important step toward a more equitable Title X program.” Numerous comments expressed specific support for the emphasis on health equity in the proposed rule. Comments expressed that the “added definition for health equity underscores the goal of ensuring that all Title X patients have the opportunity to attain their full health potential.” Many comments also expressed support for the definition of family planning services, and specifically the inclusion of “FDA-approved” contraceptive products and reinstatement of the term “medically approved” to the definition. Several comments were supportive of not

including women whose employers do not cover contraception for religious reasons in the definition of low-income. One comment expressed support for the NPRM's "returned focus on Title X's priority population—low-income clients—and removal of the 2019 rule's re-definition of 'low income' to use the program to pay for contraceptive services for any people whose employers refuse to include coverage for such services in their employer sponsored insurance due to religious or moral objections." Several comments also expressed support for using more inclusive terminology throughout the NPRM and expressed that "'client' is more reflective of the diverse population of patients served by the Title X program."

Several comments, while supportive of the definitions included in the NPRM, did request specific revisions to many of the new or revised definitions. Several comments requested that the Department explicitly include systemic racism within the definition of health equity. Another comment requested that the Department revise the definition of health equity by expanding "the umbrella term 'socially determined circumstances' to 'other circumstances that are socially, economically, demographically, or geographically determined.'" One comment requested that the Department revise the definition of adolescent-friendly services to include "developmentally appropriate services that support the healthy cognitive, physical, sexual, and psychosocial development of adolescents as they transition from childhood to adulthood and account for their unique needs, including with respect to confidentiality, legal status, and autonomy." Other comments asked the Department to revise the definition of inclusivity to include non-religious people and the intersex community. One comment requested that the definition of trauma-informed care be revised to prevent future discrimination of transgender people by "clarifying that a trauma-informed program should not result in discrimination against any population."

The Department also received several comments opposing the new or revised definitions. A few comments opposed the definition of client-centered care and felt that it raised conscience concerns. Other comments opposed the definition of family planning services and specifically opposed removing abstinence and preconception health from the definition. One comment opposed the definition and said that "medically approved" did not include natural family planning. Another

comment questioned why the definition of family planning services did not emphasize "supporting unexpected pregnancies with assistance required by families and mothers—including emotional, educational, financial, and healthcare supports." Other comments expressed general opposition to the definition of family planning services and felt that the definition included abortion and abortion-related services.

One comment stated that the definition of health equity was vague and undermined the priority for serving low-income clients. Another comment stated that the focus on health equity was "targeting minority communities to restrict pregnancy," and another stated that the focus on equity was unnecessary because of protections already included in the Constitution. One comment opposed the definition of cultural and linguistically appropriate services and expressed that "the phrase 'culturally and linguistically appropriate services' may bless health practices, based on cultural norms, that lead to negative health outcomes." One comment opposed the definition of "trauma-informed" and said it was vague and that it was not clear what was required to be trauma-informed.

One comment opposed the definition of inclusivity and felt that it would drive faith-based providers out of the program. Another comment took issue with the definition of "inclusivity" and stated that "segregation or prioritization of Title X services by protected classes such as race violates the Constitution and several civil rights laws." A few comments opposed the use of the word "client" instead of "woman" throughout the NPRM and felt that the change in language was a disservice to women. Two comments opposed removing women who cannot receive contraception from their employer because they have a religious or moral objection from the definition of low-income. A few comments opposed the definition of quality healthcare. One comment opposed including client-centered and equitable within the definition of quality. Still another comment stressed that improving the quality of healthcare is a "dynamic process" and that "this dynamism requires a nimbleness often unattainable by national requirements." The commenter requested that the definition of quality be amended to allow "maximum flexibility at the state and local level to establish standards of care."

Response: The Department appreciates the supportive comments regarding the new and revised definitions in the NPRM and believes

that clear definitions for terms used throughout the regulations are important for consistent implementation. The Department acknowledges comments requested revisions to many of the definitions; however, the Department believes that it is important to use widely accepted and commonly used definitions from other federal agencies and national medical organizations as the foundation for the regulation. For this reason, the Department will not revise the proposed definitions as requested by several comments.

The Department disagrees that the definition of client-centered care raises conscience concerns. The purpose of the rule and the definitions is to refocus the program as a client-centered one, where well-being of the patient, not the provider, is the primary goal. As stated earlier, providers may avail themselves of existing conscience protections and file complaints with OCR, which will be evaluated on a case-by-case basis as is done with other complaints.

The Department also disagrees with comments objecting to the definition of family planning services. The definition of family planning services within the NPRM is consistent with the definition of family planning services in QFP. Contrary to some of the comments opposed to the definition of family planning services, the definition does include preconception health, natural family planning, and abstinence (as a component of natural family planning). Family planning services include a broad range of services related to achieving pregnancy, preventing pregnancy, and assisting clients in achieving their desired number and spacing of children. Also, given that the focus of Title X is on helping clients achieve pregnancy, prevent pregnancy, and achieve their desired number and spacing of children, the Department responds to comments requesting that Title X provide support to clients once they become pregnant by noting that this is beyond the scope of the Title X program. Further, as is clear from section 1008 of the Title X statute, none of the funds appropriated for Title X are used in programs where abortion is a method of family planning. No court has found the decades-long practice of referral upon request to violate that prohibition.

The Department disagrees with comments expressing concern with the definitions of health equity, cultural and linguistic appropriateness, inclusive, low-income, quality, and trauma-informed. The definitions proposed in the NPRM are widely used definitions from other federal agencies and major

medical organizations. The Department also disagrees that the definition of inclusive will drive faith-based organizations out of Title X or that it will segregate services; rather, the goal is to ensure that all people can actively participate in and benefit from family planning services. Finally, the Department disagrees with comments opposing the use of the word “client” and believes that it is important that the words used in Title X fully reflect the diversity of Title X clients.

In conclusion, the Department adopts the definitions from the NPRM for this provision as final with one revision and one technical correction. Given the revisions described later to 59.5(b)(1) and 59.5(b)(6) to include reference to “clinical services providers” in the regulatory text, the Department is adding a definition for “clinical services provider” to the final rule in 59.2. The definition of clinical services provider comes from OPA’s FPAR and has been widely used as a definition for Title X grantees to guide their FPAR data collection and reporting. As taken from FPAR, a clinical services provider is defined as “physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.”

One technical correction in the final rule is to the definition of family planning services. The definition in the NPRM stated, “Family planning services include a broad range of medically approved contraceptive services, which includes Food and Drug Administration (FDA)-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.” Since the FDA does not approve contraceptive “services,” but rather approves, clears, and authorizes (for purposes of this rulemaking, “FDA-approved”) “contraceptive products,” the definition in the final 2021 rule is revised. The final definition will now read, “Family planning services include a broad range of medically approved services, which includes FDA-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling,

assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.”

In addition to this revised definition for family planning services, the definitions from the NPRM for Act, adolescent-friendly health services, client-centered care, culturally and linguistically appropriate services, family, health equity, low-income, inclusive, non-profit, quality healthcare, Secretary, service site, state, and trauma-informed are all adopted as final.

§ 59.5(a)(1). Broad Range of Acceptable and Effective Medically Approved Family Planning Methods and Services

In the NPRM, the Department proposed revising section 59.5(a)(1) of the 2000 regulation to require sites that do not offer the broad range of methods on-site to provide clients with a referral to a provider who does offer the client’s method of choice. In addition, the NPRM specified that the referral must “not unduly limit the client’s access to their method of choice.” The complete NPRM language for this provision stated, “Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a referral to the client’s method of choice and the referral must not unduly limit the client’s access to their method of choice.” The proposed revisions recognized that while an organization that offers only a single method of family planning may participate as part of a Title X project, as long as the entire project offers the broad range of methods and services, offering only a single method of family planning could impact client access.

Comments: The Department received many comments in support of section 59.5(a)(1), especially in support of the requirement that Title X projects provide a broad range of acceptable and effective medically approved family

planning methods. Many comments expressed support for reinstating the term “medically approved” to the provision. Several comments requested that the Department add more specificity to the regulations to further define what is meant by “a broad range of methods.” One comment requested that the Department “expect Title X agencies to offer ‘many’ or ‘almost all of the most commonly used’ methods, and use referrals as an option of last resort.” Another comment requested the Department to “require each site to have at least one type of each provider-administered method in stock, and to have a process in place to offer other methods of contraception by prescription if not stocked in the clinic.”

The Department also received many comments expressing concern about allowing an organization to participate as part of a Title X project if it only offers a single method of family planning, as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Several comments expressed concern that “allowing Title X sites to offer a single method of contraception conflicts with Quality Family Planning standards and HHS’ stated goals regarding quality, client-centered care, and health equity.” Several other comments requested that “if HHS continues to allow specific sites to offer a single method of contraception, HHS must clarify that the method be medically approved and effective.”

The Department received further comments regarding the language in the NPRM requiring sites that do not offer the broad range of methods and services to “provide a referral, and the referral must not unduly limit the client’s access to their method of choice.” Many comments expressed support for requiring that sites refer clients if the site does not offer the client’s method of choice. Some comments expressed concern that it was unclear what was meant by “not unduly limit the client’s access” and how the requirement would be enforced across diverse communities. Some comments expressed concern that rural communities with more limited access to refer clients to other organizations nearby would be penalized if the referral was considered to unduly limit the client’s access. Some comments asserted that requiring referrals for a client’s method of choice would result in faith-based and natural family planning providers leaving the Title X network. Several other comments expressed concern that the referral requirement was “vague and

does not go far enough.” One comment asked the Department to “clearly outline the reasons and/or circumstances under which a Title X site may be excused from offering a broad range of medically approved methods and parameters, including a maximum ‘reasonable’ distance a Title X patient would have to travel to get their method of choice.” Another comment asked the Department to closely monitor the accessibility of referrals made by Title X sites. Other comments asked the Department to provide a specific number of minutes or miles from the Title X project to the referral location and to require that referrals be only to another Title X site to ensure the same discounted services would be available.

Response: The Department appreciates the supportive comments for this provision in the 2021 rule. Since acceptable and effective medically approved family planning methods can change over time, the Department does not believe that additional specificity regarding what is meant by a broad range of methods and services is necessary within the regulatory text. Instead, the Department will provide additional guidance and technical assistance to assist grantees in complying with the regulation and ensuring access to a broad range of acceptable and effective methods and services across their service sites.

The Department acknowledges the comments expressing concern with allowing an organization to participate in a Title X project if it only offers a single method of family planning as long as the overall project offers the broad range of methods and services. For much of the Title X program’s history, including in the 2000 regulations, the regulation has included this provision. The Department believes that retaining this provision in the 2021 rule is important to ensure flexibility in addressing community needs and recognizes that not all Title X service sites may be able to provide access to all methods and services. The Department will monitor and provide technical assistance to ensure that each grantee provides access to the broad range of acceptable and effective medically approved family planning methods and services to their clients.

The Department disagrees that the referral requirement will result in faith-based and natural family planning providers leaving the Title X network. This is in part based on our longstanding experience with the program which for decades has included faith-based and natural family planning providers. The requirement for referral is intended to support

continuity of care for Title X clients. There are any number of opportunities by which this requirement could be fulfilled including directly by the clinic site or by the grantee in instances when a provider objects or lacks capacity to fulfill this requirement. An array of providers, including those that only offer a single method on-site, have successfully participated in the Title X program for decades. The Department will monitor and provide technical assistance to ensure that supporting client access to requested methods and services does not violate federal conscience laws. As part of the statutory mandate, Title X projects must provide natural family planning services, and the program will work with projects to ensure they provide all statutorily required services. Again, the Department is emphasizing in this final rule the importance of ensuring access to client-centered care. Client-centered care is defined as being respectful of, and responsive to, individual client preferences, needs, and values, and ensuring that client values guide all clinical decisions. With an emphasis on providing services that are client-centered, the default should be the fullest provision of information and services to clients.

The Department understands, based on the comments received, that it is challenging to include within the regulation a requirement that sites must provide a referral that does “not unduly limit the client’s access.” The Department fully recognizes that the referrals available to each Title X site will differ depending on what other referral resources are available within or near the community. Some communities may have access to a wide range of providers to refer clients to within the same community, while other sites may need to refer clients to organizations located farther away. Given the challenges in having one standard definition for what is considered undue burden across all Title X sites, the Department has decided to revise section 59.5(a)(1) to remove the requirement that “the referral must not unduly limit the client’s access to their method of choice.”

In addition to the revision to remove this requirement, the final rule will also include one technical correction for this provision. The Department recognizes that if a Title X site does not have the client’s method of choice available on-site, the provider may be able to provide the client with a prescription for their method of choice, rather than having to provide a referral to another provider. To better account for this, the final provision will now require sites that are

unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services to provide a prescription to the client for their method of choice or referrals, as requested. As a point-of-entry to care, Title X sites often have robust referral networks with other safety-net agencies that are attuned to the needs of the client populations that they serve. While a prescription or referral does not guarantee a client the same schedule of discounts as at a Title X site, experience suggests that the family planning safety net recognizes and takes steps to limit accessibility burdens, including financial constraints, for the clients they serve. In addition, the Department will provide additional guidance and technical assistance to grantees to help them promote accessibility and limit patient burden.

With the revisions noted above, the revised language for the 2021 rule for 59.5(a)(1) is, “Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals, as requested.” This revised language is adopted as final.

§ 59.5(a)(3). Services are Client-Centered, Culturally and Linguistically Appropriate, Inclusive, and Trauma-Informed; Protect the Dignity of the Individual; and Ensure Equitable and Quality Service Delivery Consistent With Nationally Recognized Standards of Care

In the NPRM, the Department proposed revising section 59.5(a)(3) of the 2000 regulations. In addition to providing services that protect the dignity of the individual as required in the 2000 regulations, the NPRM stated, “Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the

dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.” These revisions were aimed at increasing access and ensuring equity in all services provided, which the Department believes is especially important for the Title X program with a statutory priority on serving low-income clients. In addition, the Department believes that the revisions will result in improved services for clients.

Comments: The Department received numerous comments in support of this revised provision. Many comments expressed full support for the provision and urged the Department to adopt it as quickly as possible. Others expressed specific support for the requirement that services be client-centered: “We support that the proposed rule names the importance of using client-centered models of care.” Still others expressed specific support for the inclusion of QFP within the 2021 rule and the requirement that Title X services be consistent with nationally recognized standards of care. One comment said, “[T]he Proposed Rule will again base the standards of care for the Title X program on the QFP guidelines and require that Title X clients receive high-quality, client-centered care that includes comprehensive, medically accurate counseling and information, and referrals for any other services sought.”

The Department received a few comments opposed to this provision. One comment felt that requiring services to be client-centered, inclusive, and trauma-informed would create additional “burden on applicants and providers to ensure equity within their programs.” Another comment argued with the definition of client-centered care and believed that it violated conscience protections. Still another expressed concern that the requirement for equity in conjunction with the requirement for inclusivity would violate civil rights laws and the Constitution “by giving certain classes of people preferential treatment.”

Response: The Department appreciates the comments in support of this provision and agrees that providing services in a manner required by this provision will advance equity, increase access, improve outcomes for Title X clients, and reinforce the longstanding requirement that “[s]ervices must be provided in a manner which protects the dignity of the individual.” The Department disagrees that the requirements of this provision will result in additional burden for applicants or providers, rather the

requirements of this provision simply ensure that all Title X services are of the highest quality and align with nationally recognized standards of care. The Department also disagrees that the requirements of this provision violate conscience protections and provides a specific response to comments concerning conscience earlier in Section II. D. *Application of Conscience Statutes in Title X*. Finally, the requirements of this provision do not give preferential treatment to any clients, but rather aim to ensure that all people can actively participate in and benefit from family planning services. In conclusion, the Department adopts the language from the NPRM for § 59.5(a)(3) as final without revisions.

§ 59.5(a)(4). Services Do Not Discriminate Against any Client Based on Religion, Race, Color, National Origin, Disability, Age, Sex, Sexual Orientation, Gender Identity, Sex Characteristics, Number of Pregnancies, or Marital Status

The NPRM proposed the same regulatory text for this provision as has been included in the 2000 regulations, which read “Provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.”

Comments: The Department received several comments regarding this provision and specifically expressing concerns with the phrase “without regard of.” Several comments expressed concern with the specific phrase and stated that “if Title X providers are intended, as stated in the proposed rule, to work towards advancing health equity, it is imperative that care is delivered in a way that intentionally centers and considers the identity and needs of the patient.” Several comments requested that the Department revise the provision to instead say “provide services in a manner that does not discriminate against any patient based on religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status” which they felt better supports health equity.

Response: The Department agrees with the comments and believes that revising the language as requested more clearly meets the intent of this provision, which is to prevent discrimination in the provision of services.

In addition, the Department is updating “sex” in 59.5(a)(4) to include sexual orientation, gender identity, and sex characteristics consistent with the section 1557 of the Affordable Care Act, case law, Executive Order 13988 (86 FR 7023, Jan. 25, 2021), and Departmental

policy (<https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html>). In *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), the U.S. Supreme Court held that Title VII of the Civil Rights Act of 1964 prohibition on employment discrimination based on sex encompasses discrimination based on sexual orientation and gender identity. Courts have now begun consistently interpreting similar language—“because of sex”—in other statutes to encompass these protections. See *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 616–617 (4th Cir 2020) (relying on *Bostock* to interpret Title IX as prohibiting policy prohibiting transgender student from using bathroom consistent with his gender identity). Moreover, as the Department of Justice has recently emphasized “Discrimination against intersex individuals is similarly motivated by perceived differences between an individual’s specific sex characteristics and their sex category (either as identified at birth or some subsequent time) . . . it is impossible to discuss intersex status without also referring to sex.” Title IX (justice.gov). As a result of the case law and Administration policy, the Department adds “sexual orientation”, “gender identity”, and “sex characteristics” to 59.5(a)(4).¹¹ The revised language for the 2021 rule for 59.5(a)(4) is “Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.” This revised language is adopted as final.

§ 59.5(a)(8). Charges for Services With a Schedule of Discounts

In the NPRM, the Department proposed revising section 59.5(a)(8) of the 2000 regulations by including widely accepted billing practices from the 2014 Title X Program Requirements. The NPRM text reads, “Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C.

¹¹ This language reflects requirements on Title X projects principally engaged in healthcare activities under 42 CFR part 59. If grants for the production of informational materials were again to be made under PHSA § 1005, this definition might not apply.

9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (i) Family income should be assessed before determining whether copayments or additional fees are charged. (ii) With regard to insured clients, clients whose family income is at or below 250 percent FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.”

Comments: The Department received several comments on this provision specifically seeking closer alignment of HRSA’s (Health Resources & Service Administration) Health Center Program (authorized by Section 330 of the PHS Act) and OPA’s Title X Program to minimize administrative burden for dually funded grantees. Specifically, one comment suggested modifying the proposed language in § 59.5(a)(8)(ii) to include additional language about sliding fee discounts from the Health Center Program Compliance Manual that states that sliding fee discounts are “subject to potential legal and contractual restrictions.” Another comment lauded § 59.5(a)(8)(ii) for ensuring that clients with family income at or below 250 percent FPL do not pay more than what they would otherwise pay under the schedule of discounts; however, the comment expressed that this “requirement violates insurance contracts and contradicts the guidance of other funders (e.g., HRSA).” Yet another comment expressed the need for additional guidance specific to Title X grantees and subrecipients operating under the Health Center Program, to assist with alignment of billing practices.

Response: The Department fully supports minimizing administrative burden for grantees funded under both the Title X program and HRSA’s Section 330 Health Center Program, recognizing that providers that dually participate in the two programs have been one of the fastest growing segments of the Title X provider network. Similar to the Health Center Program’s statutory requirement that health centers must operate in a manner such that no patient shall be denied service due to an individual’s inability to pay, the Department also believes, and the Title X statute requires, that an individual’s “economic status shall not be a deterrent to participation” in Title X program services. See PHS Act sec. 1006(c). The Department does not believe that adding to this rule the commenter’s suggested language with respect to the Health Center Program Compliance Manual is warranted as it is taken out of context

and does not state the statutory requirement. The Department believes that adding language requested in the comments could hinder Title X clients who qualify for sliding fee discounts from receiving the discounts, which is contrary to Title X’s mandate of prioritizing services to low-income clients. Further, OPA clarifies how Title X grantees may remain in compliance with Title X Program requirements when integrating services with HRSA’s Health Center Program grantees and look-alikes in OPA Program Policy Notice: 2016–11: Integrating with Primary Care Providers.”

Rather than revising the regulation and risk Title X clients not receiving all discounts for which they qualify, OPA will continue to work closely with HRSA to ease administrative burden for grantees funded under both programs. The Department will provide additional guidance and technical assistance to dually funded grantees aimed at reducing administrative burden. In conclusion, the Department adopts the language from the NPRM for § 59.5(a)(8) as final without revisions.

§ 59.5(a)(9). Reasonable Measures To Verify Client Income

In the NPRM, the Department proposed adding a new section 59.5(a)(9) to include one requirement from the 2014 Title X Program Requirements that grantees take reasonable measures to verify client income, and a new requirement that grantees use client self-reported income if the income cannot be verified after reasonable attempts. The Department believes that these proposed revisions will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees.

The NPRM text reads, “Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client’s participation in another program may use those data rather than re-verify income or rely solely on clients’ self-report. If a client’s income cannot be verified after reasonable attempts to do so, charges are to be based on the client’s self-reported income.”

Comments: The Department received several comments supporting the use of self-reported income. Comments received from members of the House of Representatives stated, “[W]e support the Department’s stance that patients be allowed to self-report their income, removing an unnecessary potential barrier to care.” Other comments

expressed support that “cost should not be a barrier” to receiving services. Still other reaffirmed support that allowing use of self-reported income “will greatly improve accessibility and affordability for low-income and uninsured patients seeking care from Title X program grantees.” One comment felt that the provision did not go far enough and asked that the language “explicitly state that a client’s self-reported income is sufficient, and that providers do not need to verify client income.”

The Department also received several comments on this provision specifically seeking closer alignment between Title X and HRSA’s Health Center Program (authorized by Section 330 of the PHS Act) to minimize administrative burden for dually funded grantees. Several comments felt that allowing a client’s self-reported income in cases where a client’s income cannot be verified despite reasonable attempts is inconsistent with the Health Center Program guidance. Comments reported that “health centers have broad discretion to determine the appropriate means to assess patient income and family size. While allowing self-declaration is typical in the health center program, some health centers have opted to adopt a policy establishing that self-declaration, without supporting documentation, is not an acceptable means to verify income for every patient.”

Response: The Department appreciates the supportive comments and agrees that the requirements in this provision will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees. The elimination of barriers to Title X services for low-income clients is important to the Title X program. The Department disagrees that the requirements in 59.5(a)(9) are not compatible with HRSA’s guidance. HRSA requires health centers to operate in a manner such that no patient shall be denied service due to an individual’s inability to pay; further, HRSA Health Center Program grantees are required to establish systems for sliding fee scale eligibility that comply with statutory requirements under section 330 of the PHS Act and regulatory requirements under 42 CFR 51c.303(f) and 56.303(f), which do not preclude self-declaration of income and family size. The Department believes that the HRSA Health Center Program requirements are fully consistent with the language in § 59.5(a)(9). A strict standard of income verification at a particular health center is a choice that does not warrant weakening a standard in Title X that the

Department has created to support and reinforce the program's statutory obligation to prioritize services to persons from low-income families. In conclusion, the Department adopts the language from the NPRM for § 59.5(a)(9) as final without revisions.

§ 59.5(a)(12). State Reporting Laws

In the NPRM, the Department proposed adding 59.5(a)(12) to retain some, but not all, language from the 2019 rule on notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. The NPRM language stated, "Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws"). Title X projects must provide appropriate documentation or other assurance satisfactory to the Secretary that it: (i) Has in place and implements a plan to comply with State notification laws. (ii) Provides timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or for providers with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws."

Comments: Many comments supported the elimination of section 59.17 from the 2019 rule. Comments supported eliminating "the 2019 rule's attempt to give HHS substantial oversight over compliance with complex state reporting requirements." Many comments noted that "professionals providing services in Title X-funded sites are aware of their reporting obligations, already receive training on them, and make reports in compliance with these requirements." Other comments stressed that determining compliance with state reporting laws lies with state authorities and noted that state reporting laws "are complex and vary widely from state to state."

One comment written in opposition to the NPRM expressed that the NPRM excluded "the mandatory reporting of sex trafficking and violence by intimate partners." Another comment requested that the 2019 Title X requirement for mandatory reporting be kept fully intact.

Another comment expressed concern that the proposed rule did not include the minor age record-keeping requirements and made an assertion that "[t]his lack of record keeping serves to enable sex traffickers and abusers to continue undetected in their abuse." The comment proposed reinstatement of these requirements and further proposed rescinding the funding of any grant recipient who fails to screen for and report sexual abuse or sex trafficking.

Response: The Department agrees with comments that all Title X recipients must follow state reporting laws and must comply with mandatory reporting requirements regarding child abuse, child molestation, sexual abuse, rape, or incest. The Department disagrees with the assertion that ". . . lack of record keeping serves to enable sex traffickers and abusers to continue undetected in their abuse." States have already established specific guidelines on the details that must be included in mandatory reports. As such, the Department believes that it is not necessary to impose this additional reporting burden through Title X regulations.

Since 1999, Congress has required, through the annual appropriations bill that, "[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest." All requirements in the appropriations riders are legislative mandates for the Title X program and all Title X grantees must comply with them. The Department will continue to enforce and monitor grantee compliance with all Title X statutory requirements and legislative mandates, including the mandate that "no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

As noted above with respect to Section II. C. *Grantee and Subrecipient Compliance*, OPA explicitly states in NOFOs that all Title X grantees must comply with the Title X statute, regulations, and legislative mandates. In addition, Title X applicants certify in the application materials that they will comply with federal law, and compliance with federal law, and compliance with program statutes and appropriations act requirements is also included as a standard term of the Title X grant award. Therefore, during the application process as well as by accepting funds, grantees have assured

their compliance to the statute, regulations, and legislative mandates. Furthermore, OPA includes the legislative mandates in its grantee orientation and trainings and regularly monitors grantee compliance with the legislative mandates through grantee reporting and compliance monitoring visits. OPA has consistently documented compliance with this mandated requirement and will continue to do so. A 2005 OIG report (OEI-02-03-00530) found that OPA has informed and periodically reminded Title X grantees of their responsibilities regarding state child-abuse and sexual-abuse reporting requirements.

Given the comments received and that Title X compliance with state mandatory reporting is already required through a legislative mandate for the Title X program, the Department does not deem it necessary to include this provision within the final regulation itself. Furthermore, this provision was a part of the 2019 rule that is being rescinded as a whole because it was a set of interrelated requirements that did not promote the public health or solve any Title X compliance concerns. In conclusion, the Department removes language from the NPRM for § 59.5(a)(12) from the 2021 final rule.

§ 59.5(a)(13). Subrecipient Monitoring

In the NPRM, the Department proposed adding 59.5(a)(13) to retain some, but not all, of the language from the 2019 rule related to subrecipient monitoring and reporting. This addition required Title X grantees to report on the subrecipients and referral agencies involved in their Title X projects and to provide their plan for oversight and monitoring of their subrecipients in grantee reports.

The NPRM language stated, "Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports: (i) Subrecipients and agencies or individuals providing referral services and the services to be provided; (ii) Description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and (iii) Explanation of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients."

Comments: The Department received several comments expressing concerns with the requirements of this provision and the high reporting burden associated with it. One comment requested that section § 59.5(a)(13) be

removed completely because of the additional reporting requirements it creates. Another comment requested that the Department only require grantees to submit the additional information required by this provision for subrecipients during regular reports but not during the initial application. The comment expressed a concern that for large Title X networks, “providing a description of all referral agencies and individuals, and outlining collaborations with each subrecipient, will still pose a significant burden for Title X grantees, particularly at the time of application when applicants are often afforded 60 days or less to apply.” Many other comments requested that the Department revise the language in this provision to focus only on subrecipients and not referral agencies “due to high burden” of reporting given the size of grantee networks and the high number of possible referrals made by individual sites. One comment stressed that “under the 2000 regulations, past grantees were required to monitor each organization and ensure that their clinic sites had appropriate referrals, that they were available to all clinic personnel, and that clients’ medical charts reflected appropriate referrals given and follow-up performed. However, grantees were not required to gather every referral source and report this information to HHS. This requirement will likely create an administrative burden that could be accomplished through HHS monitoring of grantees.”

Response: It is clear from the comments received that the proposed requirements in § 59.5(a)(13) are unnecessarily burdensome for grantees and will result in Title X staff having to spend valuable time on administrative reporting that could otherwise be spent providing services to clients. The Department agrees that monitoring how grantees are involving and monitoring their subrecipients in their project and the composition of grantee referral networks can be achieved through the Department’s existing grantee compliance monitoring system. Departmental grants regulations at 45 CFR 75.352 already document the requirements for pass-through entities and specify the reporting required of grantees for all pass-through entities. Furthermore, this provision was a part of the 2019 rule that is being rescinded as a whole because it was a set of interrelated requirements that did not promote the public health or solve any Title X compliance concerns.

Given the challenges noted with this provision and the additional reporting burden it would place on grantees, the

Department has decided to remove § 59.5(a)(13) from the 2021 final rule.

§ 59.5(b)(1) Provide Medical Services Related to Family Planning

In the NPRM, the Department proposed revising section 59.5(b)(1) of the 2000 regulations to acknowledge that consultation for medical services related to family planning can be provided by healthcare providers beyond the physician. Specifically, the NPRM stated, “Provide for medical services related to family planning (including consultation by a healthcare provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.” The proposed revision acknowledged that consultation for healthcare services related to family planning may be by a physician, but may also be by other healthcare providers, specifically acknowledging participation by physician assistants and nurse practitioners.

Comments: The Department received numerous comments supporting this revised provision, specifically in support of the recognition that a broad range of healthcare providers, in addition to physicians, have an important role to play in providing medical services related to family planning. Comments expressed agreement that “other clinicians often play an important role in providing family planning counseling and other services.” In addition, numerous comments asked the Department to clarify that this provision includes a broader range of healthcare providers beyond just physician assistants and nurse practitioners, as noted in the preamble of the NPRM. One comment asked that the Department use the definition of Clinical Services Provider from FPAR. Many other comments stated that “it is important to note that ‘consultation by a [healthcare] provider’ is not and should not be limited only to the examples cited by HHS, as these CSPs represent only one facet of healthcare providers in Title X settings.”

In addition to the numerous comments related to the array of healthcare professionals that are responsible for clinical service provision in Title X, the Department also received numerous comments asking for the language of this provision to be revised to clearly reflect telehealth as an acceptable service delivery modality. Several comments expressed

the importance of telehealth, especially throughout the COVID–19 pandemic, in allowing many Title X clients to continue to safely access essential services. Many comments expressed concern with the Department’s use of the word “telemedicine” in the NPRM instead of “telehealth” and felt that telehealth refers “to a broader scope of remote healthcare services than telemedicine and includes non-clinical services like counseling and education.” Several comments specifically asked the Department to revise § 59.5(b)(1) to be clear within the regulation that family planning services can be provided “in person or via telehealth.” Other comments asked the Department to specify within the regulation that telehealth services can include “audio-only modalities” and expressed that “all forms of telehealth modalities, including audio-only must be covered to remove any barriers of access for patients.” One comment asked the Department to provide guidance to Title X grantees on how to use telehealth services to ensure access, equity, and quality.

Response: The Department appreciates the comments in support of this provision, especially those that recognize the role of a broader range of healthcare providers in delivering family planning services. It was never the Department’s intention to imply that the only healthcare providers who could provide consultation under this provision were physician assistants and nurse practitioners. Physician assistants and nurse practitioners were included in the NPRM preamble to provide examples, but not to be exclusionary. The Department agrees with comments recommending use of the definition of Clinical Services Providers from FPAR to determine who is eligible as a healthcare provider under this provision and, as noted in the discussion related to Section 59.2 *Definitions*, is adding this definition to the final rule. The FPAR definition for Clinical Services Providers includes “physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.”

The Department agrees with the comments reiterating the importance of telehealth and the role of telehealth services in expanding access to services and advancing equity. The Department had always intended for the final rule to apply to family planning services

provided in-person or via telehealth and had specifically stated in the NPRM that the Department was “readopting the 2000 regulations with revisions that will enhance the Title X program and its family planning services, including family planning services provided using telemedicine, for the future.” Telehealth has played a critical role for Title X in responding to the COVID–19 pandemic. By utilizing telehealth modalities, Title X grantees were able to continue to provide essential family planning services throughout the pandemic. With the onset of COVID–19, the vast majority of Title X grantees transitioned to some form of telehealth service delivery in order to continue providing services while limiting contact between individuals and protecting client safety. Telehealth was commonly used by Title X grantees for non-urgent visits that did not require a physical exam. Of importance, more than half of the grantees that were able to deliver telehealth during COVID–19 reported to OPA in their progress reports that they intended to continue offering telehealth services even after the pandemic ends, due to the advantages for both clients and staff.

Given the comments received, the Department believes that it is important to include language specifically in the regulatory text to clarify that telehealth services also constitute appropriate service delivery. The Department also agrees with the request to use the term “telehealth” rather than “telemedicine” to be clear that telehealth services include non-clinical services like counseling and education. While cognizant that synchronous telehealth services may be delivered through different modes of technology and that audio-only modalities may mitigate access barriers, particularly for those with limited internet and/or cellular data, the Department does not agree that the regulatory text needs to be so specific to reference the use of “audio-only modalities,” especially given how rapidly technology can change. Instead, the Department will provide additional training and technical assistance to grantees on the use of various telehealth modalities to improve access, quality, and equity.

With the revisions noted above, the revised language of 59.5(b)(1) for the 2021 rule is, “Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically

indicated, and provide for the effective usage of contraceptive devices and practices.” This revised language for § 59.5(b)(1) is adopted as final.

§ 59.5(b)(3) Community Education, Participation, and Engagement

In the NPRM, the Department proposed revising section 59.5(b)(3) of the 2000 regulations to reflect the desire to engage diverse individuals to make services accessible. Specifically, the NPRM stated, “Provide for opportunities for community education, participation, and engagement to: (i) Achieve community understanding of the objectives of the program; (ii) Inform the community of the availability of services; and (iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.” The revision added language to clarify the intent to engage diverse individuals to ensure access to equitable, affordable, client-centered, quality family planning services.

Comments: The Department received one comment expressing support for 59.5(b)(3), especially emphasizing the importance of the participation and engagement of diverse individuals in making family planning services accessible, equitable, and client-centered. The Department received one comment asking that the language of 59.5(b)(3) be revised to “be clear that the needs of adolescents and young adults” are included in community education, participation, and engagement.

Response: The Department appreciates the comments in response to this provision. Community education, participation, and engagement are important for Title X projects because they help ensure that the community is aware of the Title X program and the services available. In addition, community participation and engagement are critical to helping Title X providers better understand and center the needs and experiences of the community and the clients served. Together, community education, participation, and engagement are foundational for ensuring access, equity, and quality through the provision of Title X services.

In response to the one comment requesting a revision to the provision, the Department believes that the proposed regulatory text is broad and already includes the needs of adolescents and young adults as currently written. The Department does not believe that additional revisions are needed to the regulatory text in order to

respond to the comment received. In conclusion, the Department adopts the language from the NPRM for § 59.5(b)(3) as final without revisions.

59.5(b)(6) Services Under Direction of Clinical Services Provider

The NPRM proposed the same regulatory text for this provision as has been included in the 2000 regulations, which read, “Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.”

Comments: The Department received numerous comments requesting revisions to the regulatory text for this provision. Comments requested that the regulation expand beyond physician-only directed services. Several comments requested that the text be revised to be consistent with the revisions to § 59.5(b)(1), which recognized the importance of a broader range of healthcare providers, in addition to physicians, in providing family planning services. Several comments requested revisions to expand direction of family planning services to very specific types of healthcare providers. One comment asked that the language clarify that nurse practitioners have the authority to direct family planning programs. Another comment asked that the language be revised from physician to “licensed healthcare provider.” Still another asked that this section be revised to specifically authorize physician assistants to direct family planning services.

Several other comments were specific to advanced practice registered nurses (APRNs) and asked that the language specify that APRNs “be able to serve as the medical director (in states with full practice authority).” One commenter pointed out that “while state licensure rules vary, many states have granted full practice authority to APRNs, enabling independent practice.” Another comment requested that the Department consider whether registered nurses could direct family planning services “especially in areas of provider shortage.” A final comment asked for the text to be amended to allow services provided “under the direction of an advanced practice clinician, if the services offered are within their scope of practice and if allowable under state law.”

Response: Given the comments received, the Department agrees that having consistency between 59.5(b)(1) and 59.5(b)(6) is important to more clearly reflect the role of a broader range of healthcare providers in providing

Title X services. The Department also agrees with comments that other healthcare providers, including physician assistants and APRNs in many states, have authority to direct family planning programs and should be included within the regulation.

As stated earlier, the Department received comments in response to 59.5(b)(1) asking for more clarity on the term “healthcare providers” included in the NPRM, with many comments recommending use of the term “clinical services provider” as defined by OPA in FPAR. As a result, the Department has revised the final language for 59.5(b)(1) to use the term “clinical services provider” instead of “healthcare provider” and has revised 59.2 to include the FPAR definition of “clinical services provider” in the regulatory text. The FPAR definition for clinical services provider includes “physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.”

To ensure consistency between 59.5(b)(1) and 59.5(b)(6) as requested in the public comments, the Department has revised the language for the 2021 rule for 59.5(b)(6) to, “Provide that family planning medical services will be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.” This revised language for § 59.5(b)(6) is adopted as final.

59.5(b)(8) Coordination and Use of Referrals and Linkages

In the NPRM, the Department proposed revising section 59.5(b)(8) of the 2000 regulations to add language to include primary healthcare providers in the list of referrals and to state that referrals are to be to providers in close proximity to the Title X site when feasible. The NPRM stated, “Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.”

Comments: The Department received several comments expressing support

for revising the provision to include primary healthcare providers in the list of referrals and to require that referrals be to nearby providers, when feasible. One comment expressed support and said that “referring Title X patients to local primary care physicians would facilitate access to continuous, comprehensive healthcare.” Several other comments expressed support and stressed the existing collaborative relationships between many HRSA-funded health centers and Title X sites. Comments expressed that “referral relationships allow the health center and the Title X site to become more familiar with one another’s operations and service lines, often serving as a useful precursor to a more integral relationship in the future.”

Response: The Department appreciates the many supportive comments in response to this revised provision. The Department agrees that it is important for Title X clinics to provide referrals and linkages to a wide range of healthcare services to help facilitate access for Title X clients to needed healthcare services beyond family planning. Given that the Department received no comments expressing concern with or opposition to the proposed modification, the Department adopts the language from the NPRM for § 59.5(b)(8) as final without revisions.

§ 59.6 Suitability of Informational and Educational Material

In the NPRM, the Department proposed revising the 2000 regulations by combining requirements specific to the Information and Education Advisory Committee (“Advisory Committee”) that were in sections 59.5(a)(11) and 59.6 and consolidating all of the Advisory Committee information in one place, under section 59.6. The NPRM proposed several revisions to 59.6 to clarify that the regulation applies to both print and electronic materials (in both the title of the section and regulatory text), that the upper limit on council members should be determined by the grantee, that the factors to be considered for broad representation on the Advisory Committee match the definition of inclusivity earlier in the regulation, and that materials will be reviewed for medical accuracy, cultural and linguistic appropriateness, and inclusivity and to ensure they are trauma-informed.

Specifically, the NPRM states:

“(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials

(print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) Size. The Committee shall consist of no fewer than five members and up to as many members as the recipient determines, except that this provision may be waived by the Secretary for good cause shown.

(2) Composition. The Committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).

(3) Function. In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(ii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed;

(iii) Determine whether the material is suitable for the population or community to which is to be made available; and

(iv) Establish a written record of its determinations.”

Comments: The Department received one comment in support of the proposed revisions that expressed that “this will ensure that information and materials provided to clients are appropriate and suitable for the specific communities to be served.” Another

comment shared specific support for the requirement that grantees provide “culturally and linguistically appropriate” materials. One comment opposed to this provision expressed that the language in 59.6 “remains overly narrow and prescriptive” and recommended that the language be revised to require “a Community Advisory Board charged with a broad array of responsibilities to ensure the appropriateness of Title X services for intended communities.” Another comment opposed “underrepresented communities” in composition of the advisory council and claimed that “to the extent it results in segregation or prioritization of Title X services or committee membership by protected classes such as race, it violates the Constitution and several civil rights laws.” This same comment also opposed having the advisory committee review materials to certify that they are trauma-informed and inclusive.

Response: The Department appreciates the supportive comment in response to this provision. The role of the Advisory Committee is critically important to ensure that the information and educational materials provided to Title X clients are factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed. Engaging the community and population served in the Advisory Committee itself is a key strategy to inform the grantee about the needs and experiences of the community and population served, and to make sure that the information and education materials are appropriate for the community and population served.

The Department disagrees with the comment that the language in 59.6 is too narrow and prescriptive. The Department believes that the requirements set forth in 59.6 are critical for ensuring that informational and educational materials provided to Title X clients are factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed. In addition, the Title X statute prescribes requirements related to the informational and educational materials developed or made available under the project, including that they “will be suitable for the purposes of [Title X] and for the population or community to which they are to be made available, taking into account educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials” (PHS Act sec. 1006(d)(1)), and also prescribes requirements related

to the Advisory Committee, including that the “committee shall include individuals broadly representative of the population or community to which the materials are to be made available” (PHS Act sec. 1006(d)(2)).

The Department also disagrees with the comment that the regulation is segregating or prioritizing services or committee members. The text of the provision calls for the Committee membership to include “individuals broadly representative of the population or community for which the materials are intended. . . . Including but not limited to individuals who belong to underserved communities.” Since all communities served are different, the aim of this provision is to ensure the committee is representative of the community and population served, as required by the statute. The Department disagrees with the opposition to having the Advisory Committee review materials to ensure they are inclusive and trauma-informed. Providing information and educational materials that are inclusive and trauma-informed are a critical component of providing quality, client-centered care.

The Department does not believe that revisions are needed to the regulatory text included in the NPRM. As a result, the Department adopts the language from the NPRM for § 59.6 as final with a technical correction to include “sex characteristics”.

§ 59.7 Grant Review Criteria

In the NPRM, the Department proposed revising section 59.7 of the 2000 regulations to add one additional review criterion that the Department may consider in deciding which family planning projects to fund and in what amount, which is “the ability of the applicant to advance health equity.” Adding this new criterion to the 2000 regulations brings the total number of grant review criteria specified in the regulation from seven to eight. Advancing health equity is critical to the mission of the Title X program. The addition of this grant review criterion will help ensure that grant funds are awarded to those applicants who are best able to help the Department in achieving the goal of advancing health equity through the Title X program.

Comments: The Department received several comments in response to this revised provision asking for additional details in future funding opportunities about what the new criterion means and how it will be measured. One comment provided specific examples of how the Department could operationalize the new grant review criterion. Another comment asked the Department to

“develop additional guidance and tools that Title X sites and other healthcare organizations can readily implement” to meaningfully advance health equity. Still another comment expressed concern that the NPRM did not include an explanation “for how a Title X project can, in fact, ensure equity in general and specifically in a way that does not lead to actual discrimination based on a protected basis.”

Response: The Department appreciates the comments and recommendations received. The grant review criteria from the 2000 regulation include several criteria aimed at assessing the need, capacity, and ability of the applicant organization, including the relative need of the applicant, the capacity of the applicant to make rapid and effective use of the federal assistance, the adequacy of the applicant’s facilities and staff, the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project, and the degree to which the project plan adequately provides for the requirements set forth in these regulations. In addition, the grant review criteria from the 2000 regulation include two criteria aimed at assessing need in the communities served, including the number of clients, and, in particular, the number of low-income clients to be served; and the extent to which family planning services are needed locally.

The Department believes that adding the new grant review criterion to assess the ability of the applicant to advance health equity is important to enable OPA to more fully assess the extent to which the applicant’s project will promote health equity through the Title X services provided. Under 59.2, health equity is defined as “when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.”

Adding a focus on advancing health equity will not lead to discrimination or preferential treatment as expressed by some comments opposed to the NPRM. Rather, including a focus on advancing health equity aims to ensure that all people can actively participate in and benefit from family planning services. By advancing equity across the federal government, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone. The federal government’s goal in advancing equity is to provide everyone

with the opportunity to reach their full potential.

To measure the ability of an applicant to advance health equity, OPA could assess how the location of planned Title X service sites compares to the need for family planning services within the communities served. OPA also could assess how the applicant plans to provide services in a manner that is culturally and linguistically appropriate. OPA could assess how the project plans to monitor outcomes by clients' income, race, ethnicity, geographic location, etc., as well as how the project plans to address differences in outcomes through the Title X services provided. OPA could also ask applicants to describe the uptake of services by client demographics to identify existing disparities and to describe how they would work to reduce existing disparities in service provision. In addition, some agencies within the Department have incorporated disparity impact statements as a part of the post-grant award process. Disparity impact statements are just one example of a tool that OPA may consider in order to measure demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities. These are just examples of how this new grant review criterion could be operationalized within future NOFOs.

The Department will provide details on how all grant review criteria will be measured in future NOFOs, including the new grant review criterion on advancing health equity. The Department also plans to develop training and technical assistance products to assist family planning providers in advancing health equity.

In conclusion, the Department adopts the language from the NPRM for § 59.7 as final with one technical correction to replace "his estimate" with "an estimate" to reflect inclusive language.

§ 59.10. Confidentiality

In the NPRM, the Department proposed revising the provision of the 2000 regulations related to confidentiality, which was section 59.11 in the 2000 regulations, but is now section 59.10, to add a widely accepted practice in the Title X community, indicating that reasonable efforts must be made to collect charges without jeopardizing client confidentiality. In addition, the Department proposed adding a requirement that grantees must inform the client of any potential for disclosure of their confidential health

information to policyholders where the policyholder is someone other than the client. Since state and local laws may vary across jurisdictions (e.g., some are likely to result in notification to the policyholder that the client has received services, others provide for an "opt out" process whereby the client can elect that such a notification will not be made), this addition was added to ensure that the client understands the implications for using their insurance and the options available for them to maintain confidentiality.

Specifically, the NPRM stated, "All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client."

Comments: The Department received numerous comments in support of this provision and the proposed revisions. Many comments expressed support for restoring "the confidentiality protections that have been a hallmark of the Title X program." Several comments expressed support for allowing "providers to return to the high standard of confidentiality that all patients, including adolescents, deserve when accessing healthcare services, especially ones as potentially sensitive as family planning and sexual health." Several comments also specifically supported the new language on potential disclosure to policyholders.

The Department also received numerous comments requesting further revisions to the regulatory text for 59.10. Numerous comments urged the Department to add language to the regulatory text to clarify that "Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services."

Comments underscored that this language has been longstanding guidance from OPA for the Title X

program and is included in *OPA Program Policy Notice 2014-01: Confidential Services to Adolescents*. One comment stated, "We encourage you to take all possible steps when finalizing the rule to ensure that adolescents are treated with the same client-centered approach as all other patients at Title X-funded health centers." In addition, many comments generally opposed the removal of language from the regulation that encouraged family participation in the decision of a minor patient to seek family planning services and requested that the language be added back into the final regulation.

Several other comments expressed concern with a new rule from the HHS Office of the National Coordinator for Health Information Technology (ONC) about Electronic Health Records and information blocking. Several comments requested that the Department confirm in the final rule that withholding of sensitive information in compliance with 59.10 would "fall within the ONC rule's privacy exception and would not constitute information blocking."

Response: The Department appreciates the comments in support of the revised provision in the NPRM. The Department agrees with comments to add specific language to the final rule regarding adolescent confidentiality to reflect Title X legal requirements. Since 1981, the Title X statute has required that, "to the extent practical, [grantees] shall encourage family participation" in Title X projects. 42 U.S.C. 300(a). However, such involvement is not mandatory and grantees are required to protect clients' confidentiality. Specifically with respect to adolescents, courts have for decades recognized minors' rights to receive confidential services under the Title X program. See, e.g., *Planned Parenthood Federation of America, Inc. v. Heckler*, 712 F.2d 650 (D.C. Cir., 1983) (Title X expressly protects minors' rights to seek services confidentially). See also *OPA Program Policy Notice 2014-01: Confidential Services to Adolescents*.

The Department does not agree that specific language needs to be added to the final rule to clarify the applicability of the ONC rule to Title X. Instead, as described below related to section 59.12, OPA suggests that grantees seek guidance from ONC with respect to the applicability of the information-blocking provision, as ONC administers this rule and, thus, would be in the best position to interpret it. With this revision, the final language in the 2021 rule for 59.10 is, "(a) All information as to personal facts and circumstances obtained by the project staff about

individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.

(b) To the extent practical, Title X projects shall encourage family participation.¹² However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

This revised language for § 59.10 is adopted as final.

§ 59.12 Other Applicable Regulations

In the NPRM, the Department included the same regulatory text as had been included in section 59.10 of the 2000 regulations, which is a list of additional HHS regulations that apply to the Title X family planning services program. The NPRM proposed a technical correction to update the list of applicable regulations by adding 45 CFR part 87.

Comments: Many comments that generally support the rule disagree with the proposed technical correction to section 59.12, which includes a reference to 45 CFR part 87 (“Equal Treatment for Faith-based Organizations”) in the list of regulations that apply to the Title X program. Such comments argued that this rule does not apply to Title X because the previous administration explicitly declined to apply this rule to Title X in the faith-based organizations rule issued on December 17, 2020 (see 85 FR 82037, 82117). Additionally, these comments argued that 45 CFR part 87 does not apply to the Title X program because it is a health services program, and 45 CFR part 87 only applies to social services programs; thus, the reference to this regulation should be removed from

section 59.12 of the final rule. Other comments argued that, if the Department is planning to make technical corrections to update the list of regulations that apply to the Title X program, it should take the opportunity to clarify the applicability of 45 CFR part 92 (“Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Programs or Activities Administered by the Department of Health and Human Services Under Title I of the Patient Protection and Affordable Care Act or by Entities Established Under Such Title”) as well as the statute under which it was authorized, section 1557 of the Affordable Care Act. These comments stipulated that if the Department makes changes to this regulation in the future, section 59.12 should be updated at that time to include 45 CFR part 92 on this list of applicable regulations.

Comments opposing the rule agreed with the inclusion of 45 CFR part 87 in section 59.12, but questioned why the Department did not include an explanation for deleting references to the now-superseded 45 CFR part 92 (“Uniform administrative requirements for grants and cooperative agreements to state and local governments”). These comments also argued that the Department should include a reference to 45 CFR 88 (“Protecting Statutory Conscience Rights in Health Care; Delegations of Authority”) on the list of applicable regulations, as it will apply to the Title X program once related litigation is resolved.

Response: The Department appreciates the comments addressing the proposed technical corrections to 45 CFR 59.12, but has decided to eliminate that section from the final rule in its entirety. Since the regulations that apply to the Title X program will apply of their own accord, whether or not they are cross-referenced in 42 CFR part 59, subpart A, the Department has concluded that the list of applicable regulations in 59.12 serves no useful purpose and, in contrast, may be misleading. The Department is concerned that since regulations are amended frequently, any current listing of applicable regulations could soon become outdated. Additionally, while all of the longstanding Departmental regulations, such as those prohibiting discrimination, still apply, the Department is concerned that the 59.12 list may provide a false impression that only the regulations included in this section apply to the Title X program. The Department believes that Title X

grantees can more accurately assess which regulations apply to the Title X program by reviewing the regulations at issue and, in some instances, seeking guidance from the agencies which administer them. For example, several comments, in the context of addressing the confidentiality provisions, questioned the applicability of the information-blocking provisions in the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” rule (85 FR 25642, May 1, 2020). As that rule is administered by the HHS Office of the National Coordinator for Health Information Technology (ONC), ONC would be in the best position to interpret that rule.

Most importantly, OPA provides information to Title X grantees regarding which regulations apply to their Title X programs and is committed to providing ongoing guidance and assistance as questions arise. OPA includes information about applicable regulations in grant documents, such as NOFOs and Notices of Award, and in technical assistance webinars. Given that grantees can receive accurate and up-to-date information from OPA about which regulations apply to their Title X programs, the Department has decided to delete section 59.12 from the final rule.

III. Regulatory Impact Analysis

A. Introduction

The Department has examined the impact of the final rule under Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, Executive Order 13132 on Federalism, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct the Department to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Department believes that this final rule is not an economically significant regulatory action as defined by Executive Order 12866 because it will not result in annual effects in excess of \$100 million.

The Regulatory Flexibility Act requires the Department to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule will lessen

¹² 42 U.S.C. 300(a) states: “To the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.”

administrative burdens for grantees of all sizes. Therefore, the Secretary certifies that the final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 605.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires the Department to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications. The final rule will not have a significant impact on state funds as, by law, project grants must be funded with at least 90 percent federal funds. 42 U.S.C. 300a–4(a). The Department has determined that this final rule does not impose such costs or have any federalism implications. The Department expects that while some states may not support the policies contained in this final rule, many states and local health departments will support the policies contained in this final rule, and that it will increase participation by states (many of which withdrew as a result of the 2019 rule).

B. Summary of Costs, Benefits and Transfers

This final rule will revise the regulations that govern the Title X family planning services program by revoking the 2019 rule and readopting the 2000 regulations with several modifications. This approach will allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

We predict that this final rule will increase the number of grantees receiving Title X funds. In turn, the additional service sites supported by funding will result in additional clients served under the program. These clients receive access to contraception, and

public health screening including clinical breast exams, Papanicolaou (Pap) testing, and testing for STIs. These services result in improved family planning and birth spacing, earlier detection of breast and cervical cancer, and earlier detection of sexually transmitted infections including chlamydia, gonorrhea, syphilis, and human immunodeficiency virus (HIV), all of which correlate to net savings for the government. This screening and testing can result in significant cost savings from earlier treatment and other interventions. This final rule will also increase the diversity of grantees receiving funds, including geographic diversity to states that do not currently have a Title X grantee.

The final rule will also focus grantees on providing services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery. This focus is especially important for the Title X program that prioritizes services for low-income clients.

This regulatory impact analysis reports the activity occurring at Title X-funded sites to provide policymakers with this information. However, the direct impact within the program does not account for services that continue to be provided at sites not receiving Title X funding, filling the gap left by providers that withdrew from the program following the restrictions placed on funding included in the 2019 rule.

C. Comments on the Preliminary Economic Analysis and Our Responses

On April 15, 2021, the Department issued a proposed rule to revise regulations relating to the Title X program. The Department prepared a preliminary regulatory impact analysis (PRIA) for the proposed rule. Many comments were outside the scope of this rule. The paragraphs below describe and respond to the comments received on the PRIA.

Summary of comments addressing the PRIA that were generally opposed to the rulemaking:

Several of the comments suggested that the Department used flawed data in its forecasts or failed to account for COVID–19 in the PRIA. Several of the comments suggested that the Department does not have data to assess the effect of the 2019 rule, arguing that COVID–19 is a complicating factor. Several comments noted that clients served under the Title X program declined between 2009 and 2018, suggesting long-term trends can account

for some of the reduction in clients served under the 2019 rule. Other comments noted that long-term demographics trends are responsible for the decline in services, such as rise in median household income, rise in individuals with private insurance, and more diverse options available in the healthcare market.

Several of the comments suggested that grantees withdrawing from the program may not have resulted in a decline in services, and that some services were continued with state and private funds. Several comments pointed out that some states saw an increase in clients after the 2019 rule. One comment argued that, when one of two Ohio grantees left the program, the remaining grantee prevented a gap in coverage.

Responses to comments addressing the PRIA that were generally opposed to the rulemaking:

The primary estimate of the baseline Title X service grantees, subrecipients, service sites, and clients served are derived from calendar year 2019 figures, which predate COVID–19. The PRIA’s estimate of the likely effect of the proposed rule is to gradually return to the level of grantees, subrecipients, service sites, and clients that the program supported in calendar years 2016 to 2018, which also predates COVID–19. COVID–19 may complicate attempts to precisely estimate the magnitude of the effect of the 2019 rule on the Title X program, but pre-pandemic data from calendar year 2019 preceding COVID–19 reveals a significant drop-off in grantees, subrecipients, service sites, and clients supported by the program, which are contrary to the predictions in the 2019 rule.¹³ The Department acknowledges the uncertainty in the forecast of the baseline scenario of no regulatory action by including a sensitivity analysis in the PRIA. The upper-bound forecast of 3,095,666 clients served annually by the Title X program under the baseline scenario of the 2019 rule is well below the approximately 4 million clients served during calendar years 2016 to 2018.

The Department disagrees with the suggestion that long-term trends drove the reduction in clients served under the 2019 rule. Between calendar years

¹³ If adjustment to the requirements of the 2019 rule took time for grantees and prospective new grantees (and possibly continues to do so), then immediate post-issuance difficulties in obligating Title X funds could ease over the years, which would in turn lead to a trend back toward pre-2019 Title X service levels even in the analytic baseline. However, the effects of the COVID–19 pandemic would obscure, in the available data, whether such trends are present or absent.

2009 and 2014, the number of clients reported served by the Title X program declined from 5.2 million to 4.1 million, with an average annual decline in clients served by about 211 thousand per year. Between calendar years 2014 and 2018, the number of clients served fell more gradually, with an average annual decline in clients served of about 48 thousand per year. In calendar year 2019, the number of clients served fell by about 844 thousand. The Department believes it is appropriate to attribute the bulk of the reduction in clients served during calendar year 2019 to the 2019 rule.

The Department agrees with the comments that state and private funding likely averted some of the public health consequences that would have otherwise occurred in the immediate time period following implementation of the 2019 rule. The Department acknowledged this limitation in the PRIA and noted that one effect of the proposed rule would be “transfers (for example, if Title X newly funds medical services that would, in the absence of the proposed rule, be provided by charitable organizations or other private payers).” The Department noted that several states contributed emergency or one-time funds. It is not clear whether state or private funding will be available for the full-time horizon of the analysis, which begins in calendar year 2022.

While the PRIA reported that “seven states (CO, DE, KY, ND, NM, NV, TX) experienced an increase in the number of Title X *clinics* after the 2019 regulatory change,” this observation is different than the claim about increases in *clients*. Colorado, Delaware, Kentucky, North Dakota, New Mexico, and Texas all saw declines in the number of female users served in 2019 and 2020 compared to 2018 (male users saw declines as well). Nevada increased the number of female users from 9,236 in 2018 to 11,156 in 2019, and again to 11,190 in 2020. The specific claim about Ohio cannot be supported with the available data. Ohio Title X grant recipients reported 83,497 female clients served in 2018, dropping to 68,669 in 2019, and dropping further still to 27,322 in 2020. Similarly, given the implementation of the 2019 rule occurred midway through the calendar year, the 2019 data likely mask the full negative impact of the 2019 rule that year.

Summary of comments addressing the PRIA that were generally supportive of the rulemaking:

Several comments agreed with the observation in the PRIA that the 2019 rule resulted in a reduction in grantees and clients served under the Title X

program. Several comments gave examples of states or other entities that saw a decrease in clients served. Several comments discussed the disproportionate impact the 2019 rule had on low-income individuals, individuals in rural communities, people of color, and other populations. Several comments discussed the impact of the 2019 rule on the quality of family planning services outside the Title X program, as well as the financial impact on clients receiving services outside the Title X program. Several comments argued that other sources of funding besides the Title X program, including state funding, would not be reliable sources of funding in the future.

Responses to comments addressing the PRIA that were generally supportive of the rulemaking:

The Department appreciates the specific examples provided in comments and agrees with the assessment that the 2019 rule resulted in a reduction in grantees and clients served at the national level, and that these effects were more pronounced in certain regions, communities, and demographic groups. The PRIA concluded, and this regulatory impact analysis affirms, that this rulemaking will likely result in an increase in clients served within the Title X program compared to a baseline of no further regulatory action. The Department also maintains the finding in the Further Discussion of Distributional Effects Section in the PRIA in this analysis that the effects of this final rule will accrue approximately in proportion with income and race and ethnicity figures typically served by the Title X program.

The Department agrees that services provided outside the Title X program were not always identical to Title X-funded services. While some providers were able to provide reproductive health services in the absence of Title X funding, comments disclose that they were not providing the same services provided in Title X program. Specifically, commenters suggested that services provided outside of the Title X program did not follow the same standards as in Title X, and that the schedule of discounts and subsidies were not applied as required in the Title X program.

The Department agrees with the comments that other sources of funding besides the Title X program may not be reliable sources of funding over calendar years 2022 through 2026, the time horizon of the PRIA and this final regulatory impact analysis. The Department has expanded the discussion of this point in the analysis.

Comments Received in Response to Executive Order 13132 Federalism Review

Comment: Several comments were critical of the Regulatory Impact Analysis, stating that it ignores the federalism implications of the proposed rule. These comments argued that the proposed rule compels states to adopt policies that conflict with their own laws, particularly with regard to subrecipient restrictions that several states have put in place, and other state-described “integrity requirements.” Additionally, several comments raised concerns that the Department did not extend the comment period to specifically study the federalism impacts. Other comments expressed a belief that the proposed rule would have no federalism effects as it is a discretionary grant program in which states can choose to participate or not.

Response: While the Department agrees that states have an interest in enforcement of their statutes, it believes that this final rule respects federalism, as it does not interfere with state laws. As noted previously, the Department has decided not to include a subrecipient nondiscrimination provision in the final rule at this time and, thus, concerns raised by these comments about harm to state program integrity requirements or a need to extend the deadline to assess the impact of this harm are now moot.

Additionally, while states are eligible to apply for Title X grants, the Title X statute was not enacted as a federal-state cooperative statute, as is made clear by the eligibility of nonprofit, private entities to apply for grants directly. And, since the Department is free to attach reasonable conditions to the awarding of funds to carry out best its statutory goals and these conditions only apply to the receipt of federal Title X funds, states that object to the rule requirements or believe that there is a conflict with state law priorities are free to opt out of the federal grant program. Thus, the final rule does not interfere with state laws or have federalism implications, as state laws are only implicated if those states with contrary state laws wish to apply for Title X funds.

D. Summary of Changes

The Department has revised the economic analysis of impacts to account for additional information, newer data, and in response to comments. Many of the estimates and Tables have been updated to account for minor revisions to the calendar year 2020 data. For example, Table D1 now identifies 75

Grantees, 867 Subrecipients, 3,031 Service Sites, and 1,536,743 Clients Served, compared to 73 Grantees, 803 Subrecipients, 2,682 Service Sites, and 1,536,744 Clients Served reported in the PRIA. These revised estimates carry through to other estimates and Tables.

As described in greater detail in the Preamble, the final rule adopts eight of the fourteen revisions initially proposed in the NPRM and nine of the ten technical corrections initially proposed in the NPRM as final without additional changes. Based on the comments received in response to the NPRM and a subsequent, new interpretation by the Department since the NPRM was issued, the final rule includes nine additional revisions and six additional technical corrections compared to what was proposed in the NPRM. This analysis has been updated to be consistent with these changes, but these changes do not substantially alter the estimates of the quantified economic impacts.

E. Final Economic Analysis of Impacts

a. Background

The Title X family planning program, administered by the U.S. Department of Health and Human Services (HHS), Office of Population Affairs (OPA), is the only federal program dedicated solely to supporting the delivery of family planning and related preventive healthcare. The program is designed to provide “a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)” with priority given to persons from low-income families. In addition to offering these methods and services on a voluntary and confidential basis, Title X-funded service sites provide

contraceptive education and counseling; breast and cervical cancer screening; STIs and HIV testing, referral, and prevention education; and pregnancy diagnosis and counseling. The program is implemented through competitively awarded grants to state and local public health departments and family planning, community health, and other private nonprofit agencies. In fiscal year 2021, the Title X program received approximately \$286.5 million in discretionary funding.¹⁴

On March 4, 2019, HHS published a final rule to “prohibit family planning projects from using Title X funds to encourage, promote, provide, refer for, or advocate for abortion as a method of family planning; require assurances of compliance; eliminate the requirement that Title X projects provide abortion counseling and referral; require physical and financial separation of Title X activities from those which are prohibited under section 1008; provide clarification on the appropriate use of funds in regard to the building of infrastructure, and require additional reporting burden from grantees.”

b. Market Failure or Social Purpose Requiring Federal Regulatory Action

The regulatory impact analysis associated with the 2019 rule predicted that the additional restrictions on grantees would result in “an expanded number of entities interested in participating in Title X.” Further, the analysis suggested the 2019 rule would result in “enhanced patient service and care.” Contrary to these predictions, during the initial period of the 2019 rule’s implementation, the policy appears to have had the opposite effect. As described in greater detail in the Baseline section, the restrictions

included in the 2019 rule are associated with a substantial reduction in the number of Title X grantees, subrecipients, and service sites, resulting in a corresponding reduction in total clients served. The Department is compelled to act quickly to ameliorate these negative consequences by promulgating this final rule since the Title X program serves a low-income population that is particularly vulnerable to losing access to these services. This final rule is needed to improve the functioning of government and the effectiveness of the Title X program.

c. Purpose of the Rule

This final rule will revise the regulations that govern the Title X family planning services program by revoking the 2019 rule and readopting the 2000 regulations with several modifications. This approach will allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

d. Baseline Conditions and Impacts Attributable to the Rule

The Department adopts a baseline that assumes the requirements of the 2019 rule remain in place over the period of our analysis. To characterize the real-world impact of the Title X program under this regulatory approach, the Department developed an annual forecast of grantees, subrecipients, service sites, and total clients served. The key inputs to the forecast are historical data on Title X service grantees. For calendar years 2016 to 2020, this information is summarized in the 2020 Title X Family Planning Annual Report.

TABLE D1—TITLE X SERVICE GRANTEES

Year	2016	2017	2018	2019	2020
Grantees	91	89	99	100	75
Subrecipients	1,117	1,091	1,128	1,060	867
Service Sites	3,898	3,858	3,954	3,825	3,031
Clients Served	4,007,552	4,004,246	3,939,749	3,095,666	1,536,743

Source: Title X Family Planning Annual Report, 2020: Exhibit A–2a.

The data for calendar years 2016–2019 included all grantees, subrecipients, and service sites operating at any time during the year. The implementation of the 2019 rule occurred mid-year in 2019. Following this regulation, 19 grantees, 231 subrecipients, and 945 service sites withdrew from the Title X program. The

reduced number of grantees, subrecipients, services sites, and clients served observed in 2019 and 2020 cannot be explained by a reduction in discretionary funding for the program, which has remained constant at \$286.5 million throughout this time period. Since the 2019 figure includes clients served by these service sites for more

than half of the year, adopting 3.1 million clients served as an annual forecast would likely overstate activity in the program under the current regulations. Indeed, preliminary figures for 2020 approximate that only 1.5 million clients were served. However, this figure likely represents an underestimate for a typical year of the

¹⁴ Does not include supplemental funding.

program under the current regulations since services were likely disrupted by the ongoing public health emergency.

As the primary estimate, the Department adopts 2,512,066 clients served as the baseline annual impact of Title X under the policies of the 2019 rule. This 2.5 million-figure corresponds to the number of clients served in 2019 among remaining grantees as of March 2021. For comparison, this primary estimate represents a 37 percent reduction in clients served compared to the average of clients served from 2016 to 2018. In the Uncertainty and Sensitivity Analysis Section, the Department adopts the 1.5 million-client figure as a lower-bound estimate, and 3.1 million clients as an upper-bound estimate of the annual program impact under the baseline.

Table D2 summarizes the baseline forecast for the same categories of historical data presented in Table D1. The Department adopts the current count for grantees, subrecipients, and service sites and assumes constant funding and that these figures will be constant over the time horizon of this analysis.

TABLE D2—BASELINE FORECAST OF TITLE X SERVICES

Baseline forecast	Annual
Grantees	75
Subrecipients	867
Service Sites	3,031
Clients Served	2,512,066

In addition to the reduction in grantees, subrecipients, service sites, and total client served, the Department notes that six states currently have no Title X services, including HI, ME, OR, UT, VT, and WA. There are six additional states that have limited Title X services, including AK, CT, MA, MN, NH, and NY.¹⁵

In line with the reduction in clients served under the 2019 rule, data also reveal a significant drop in services provided. For example, when comparing 2019 figures to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008

fewer clients received intrauterine devices (IUDs). For oral contraceptives and IUDs, this was a 27 percent reduction, and for hormonal implants, a 21 percent reduction. These percentages are similar in magnitude to the 21 percent reduction in clients served in 2019 compared to 2018. Additionally, 90,386 and 188,920 fewer Pap tests and clinical breast exams, respectively, were performed in 2019 compared to 2018. Confidential HIV tests decreased by 276,109. Testing for STIs decreased by 256,523 for chlamydia, 625,802 for gonorrhea, and 77,524 for syphilis. Appendix A of the FPAR contains national annual trends for many of the services discussed above. The reductions in services reported in 2019 compared to 2018 represent the largest year-over-year reductions in services for each reported measure since at least 2014. Similar to the earlier discussion relating to long-term trends relating to clients, we attribute the bulk of the reductions to these services to the 2019 final rule.

For the forecast of services provided under the baseline scenario, the Department adopts the percentage of clients receiving each service in the 2019 Title X Family Planning Annual Report. For example, in 2019, about 23 percent of female clients received a clinical breast exam. The Department assumes the same share of clients will be served by Title X for screening and STI testing. Table D3 reports the best estimate of the annual services provided under the baseline scenario. These services are described in greater detail later in this Section.

TABLE D3—BASELINE TITLE X CANCER SCREENING AND SEXUALLY TRANSMITTED INFECTION TESTING

Year	Annual
Clinical Breast Exams	509,550
Pap Tests	443,087
Chlamydia Test	1,266,508
Gonorrhea Test	1,420,198
Syphilis Test	536,619

TABLE D3—BASELINE TITLE X CANCER SCREENING AND SEXUALLY TRANSMITTED INFECTION TESTING—Continued

Year	Annual
Confidential HIV Test	777,536

Source: Calculations based on Title X Family Planning Annual Report, 2019: Exhibits 26 and 29.

The Department predicts that the main effect of the final rule would be to return to Title X program impact levels observed prior to the 2019 rule. The estimates of the long-run equilibrium of grantees, subrecipients, service sites, and total clients served are informed by the data from 2016 to 2018, the last three years of data that are unaffected by the declines experienced following the 2019 rule. Specifically, the Department adopts the average across these three years as the long-run estimates. These averages are 93 grantees, 1,112 subrecipients, 3,903 service sites, and approximately 4.0 million clients served.

To complete the forecast of the policy scenario, the Department assumes that it will take two years for program participation and clients served to achieve the long-run equilibrium estimates. This two-year phase-in is consistent with a scenario in which most service sites that withdrew from the Title X program have remained open, with some operating at a lower capacity, than they did prior to the 2019 rule. It is also consistent with an expectation that many of the grantees and service sites that withdrew from the program would be able to rejoin if the NPRM issued on April 15, 2021, were finalized. In year one, following the effective date of the proposed rule, the number of clients served would increase to approximately 3.2 million. In year two, this number would increase again to approximately 4.0 million and remain constant for the duration of the analysis. These figures are presented in Table D4. The Department acknowledges uncertainty in this estimate and includes a discussion in the Uncertainty and Sensitivity Section, below.

TABLE D4—POLICY SCENARIO FORECAST OF TITLE X SERVICE GRANTEEES

Year	2022	2023	2024	2025	2026
Grantees	84	93	93	93	93
Subrecipients	990	1,112	1,112	1,112	1,112
Service Sites	3,467	3,903	3,903	3,903	3,903
Clients Served	3,247,958	3,983,849	3,983,849	3,983,849	3,983,849

¹⁵ As noted earlier, seven states (CO, DE, KY, ND, NM, NV, TX) experienced a meaningful increase in

the number of Title X clinics after the 2019 regulatory change.

To characterize the effect of the final rule, the Departments compares the policy scenario forecast to the baseline forecast described in the previous section. Table D5 reports the difference between these two scenarios, which

represents the net effect of the proposed rule. For example, in year one after this rule is effective, the number of clients served would increase by approximately 736,000 as compared to the baseline scenario. Approximately 88 percent of

clients served in 2016 to 2018 are female, and the Department uses this percentage to estimate the increase in clients served by sex under the policy scenario.

TABLE D5—EFFECT OF THE PROPOSED RULE ON TITLE X SERVICES

Year	2022	2023	2024	2025	2026
Increase in Grantees	9	18	18	18	18
Increase in Subrecipients	123	245	245	245	245
Increase in Service Sites	436	872	872	872	872
Increase in Clients Served	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Female	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Male	86,896	173,791	173,791	173,791	173,791

Clients served under the Title X program experience outcomes that include reducing unintended pregnancy through greater access to contraception. The averted unintended pregnancies translate to a reduction in unplanned births, a reduction in abortions, and reduction in miscarriages. Also, Title X clients receive cancer screenings and testing for STIs. These screenings and testing can identify treatable conditions, improving the quality of life and extending the lives of beneficiaries. In the case of STIs, additional testing and corresponding earlier treatment can reduce the likelihood of worse health outcomes and future infertility resulting from those infections. This final rule will expand service to socioeconomically disadvantaged populations, most of whom are female,

low-income, and young. The Department discusses this in greater detail in the Section on Distributional Effects.

To further explore the likely effect of the Title X program on unintended pregnancy, we rely on existing methodology for estimating number of unintended pregnancies prevented each year among U.S. women who depend on publicly funded family planning services.¹⁶ Among this subgroup of women who use any method of contraception, 46 in 1,000 women are expected to experience an unintended pregnancy. This figure can be compared to 296 unintended pregnancies per 1,000 women who are unable to access publicly funded family planning services. The Department applies this estimate of a reduction of 250 unintended pregnancies per 1,000

contraception clients to the number of additional female clients served under the Title X program who adopt any method of contraception.

For year one, the analysis reflects multiplying 735,892 clients by 88 percent to yield 648,996 female clients. Among female clients, approximately 14 percent indicate they are not using a method of contraception, according to figures in the 2019 Title X Family Planning Annual Report. The analysis reduces the potential number of clients that would potentially reduce the likelihood of an unintended pregnancy by 14 percent to yield 558,205 clients expected to benefit from a contraceptive method. Approximately 47 percent of unintended pregnancies result in births, 34 percent in abortion, and 19 percent in a miscarriage.¹⁷

TABLE D6—EFFECT OF THE PROPOSED RULE ON TITLE X-ASSOCIATED CONTRACEPTION

Year	2022	2023	2024	2025	2026
Clients Served	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Women Served	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Women Served Using Contraception	558,205	1,116,411	1,116,411	1,116,411	1,116,411

Unintended pregnancies increase the risk for poor maternal and infant outcomes. Women who give birth following an unintended pregnancy are less likely to have benefitted from preconception care, to have optimal spacing between births, and to have been aware of their pregnancy early on, which in turn makes it less likely that

they would have received prenatal care early in pregnancy.^{18 19}

Title X funding recipients also perform preventive health services such as cervical and breast cancer screening, and testing for STIs, including chlamydia, gonorrhea, syphilis, and HIV. Table D7 presents the effect of the final rule on Title X-associated cervical and breast cancer screenings. These

figures are calculated by multiplying the number of additional women served by the program in each year by approximately 23 percent for clinical breast exams, of which five percent result in a referral for further evaluation; and 20 percent for Pap testing, of which 13 percent with a result of atypical squamous cells (ASC) that require further evaluation and possibly

¹⁶Jennifer J. Frost and Lawrence B. Finer (2017). Memo entitled “Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula.” <https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf>. Accessed on March 14, 2021.

¹⁷Jennifer J. Frost, Lori F. Frohwirth, Nakeisha Blades, Mia R. Zolna, Ayana Douglas-Hall, and Jonathan Bearak (2017). “Publicly Funded Contraceptive Services at U.S. Clinics, 2015.” https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf. Accessed on March 14, 2021.

¹⁸Jessica D. Gipson, Michael A. Koenig, and Michelle J. Hindin. “The Effects of Unintended

Pregnancy on Infant, Child, and Parental Health: A Review of the Literature.” *Studies in family planning* 39.1 (2008): 18–38. Web.

¹⁹Power to Decide. *Maternal and Infant Health and the Benefits of Birth Control in America*. Accessed on March 8, 2020 from <https://powertochoose.org/sites/default/files/resources/supporting-materials/getting-the-facts-straight-chapter-3-maternal-infant-health.pdf>.

treatment, and one percent of which have a high-grade squamous intraepithelial lesion (HSIL)²⁰ or higher, indicating the presence of a more severe condition.

Clinical breast exams can identify patients requiring further evaluation of an abnormal finding. Pap tests (or pap smear tests) can detect precancers and cervical cancer cells and can also be tested for viral infections that can turn

into cervical cancer. At a population level, these screenings save lives by helping patients identify cancer earlier and by preventing other conditions from developing into cancer.

TABLE D7—EFFECT OF THE FINAL RULE ON TITLE X-ASSOCIATED CERVICAL AND BREAST CANCER SCREENING ACTIVITIES

Year	2022	2023	2024	2025	2026
Clinical Breast Exams	149,269	298,538	298,538	298,538	298,538
Referred	7,463	14,927	14,927	14,927	14,927
Pap Tests	129,799	259,598	259,598	259,598	259,598
Tests with ASC or higher	17,304	34,609	34,609	34,609	34,609
Tests with HSIL or higher	195	391	391	391	391

Table D8 presents the effect of the proposed rule on Title X-associated testing for STIs among female clients. These are calculated by adopting estimates that 49 percent of women are

tested for chlamydia, 55 percent for gonorrhea, 19 percent for syphilis, and 28 percent for HIV. Table D9 presents the same information for men. The share of male clients tested for these

infections are the following: 61 percent for chlamydia, 68 percent for gonorrhea, 39 percent for syphilis, and 53 percent for HIV.

TABLE D8—ADDITIONAL WOMEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia	318,008	636,016	636,016	636,016	636,016
Gonorrhea	356,948	713,895	713,895	713,895	713,895
Syphilis	123,309	246,618	246,618	246,618	246,618
Confidential HIV	181,719	363,438	363,438	363,438	363,438

TABLE D9—ADDITIONAL MEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia	53,006	106,013	106,013	106,013	106,013
Gonorrhea	59,089	118,178	118,178	118,178	118,178
Syphilis	33,889	67,779	67,779	67,779	67,779
Confidential HIV	46,055	92,109	92,109	92,109	92,109

Table D10 reports the additional total clients tested for STIs under Title X. These tests can identify treatable conditions that can cause discomfort, permanent damage to reproductive systems including infertility, and in certain cases, death. The 2019 Title X Family Planning Annual Report indicates confidential HIV testing identifies a positive case for

approximately 0.38 percent of all HIV tests performed. Under the final rule, testing under Title X is estimated to identify an additional 873 positive cases of HIV in the first year. In subsequent years, this estimate increases to 1,745. Testing for these STIs can also reduce the likelihood that an individual will spread an infection. In addition to testing, Title X-funded service sites also

provide HIV/AIDS prevention education. Pre-exposure prophylaxis (PrEP) has emerged as an effective HIV prevention strategy for individuals who are most at risk, and the inclusion of PrEP in the HIV prevention services provided at Title X sites is becoming an increasingly important method for protecting individuals of all ages from acquiring HIV.

TABLE D10—ADDITIONAL CLIENTS TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia	371,014	742,029	742,029	742,029	742,029
Gonorrhea	416,037	832,074	832,074	832,074	832,074
Syphilis	157,199	314,397	314,397	314,397	314,397
Confidential HIV	227,774	455,547	455,547	455,547	455,547
Positive Test Results	873	1,745	1,745	1,745	1,745

Additional services of the type provided under Title X will likely result

in reduced costs to taxpayers in line with a reduction in unintended

pregnancies, pre-term and low birth weight births, STIs, infertility, and

²⁰ HSIL is the abnormal growth of certain cells on the surface of the cervix.

cervical cancer. One report estimates that each dollar spent on these services results in a net government saving of \$7.09.²¹ We do not replicate the calculations, but note that they are derived from cost savings associated with averting unintended pregnancy and complications such as pre-term and low birth weight births. These cost savings are also derived from detecting and treating STIs that would have resulted in more serious outcomes, including infertility, cancer, and death.

In addition to the effects described above, the final rule will also enhance the equity and dignity associated with access to family planning services provided by Title X. A recent research brief summarized interviews with 30 women sharing their experiences with contraceptive access, providing suggestive evidence that birth control has an important positive impact on women's lives. Interviewees noted that birth control allowed women to "to pursue academic and professional goals, achieve financial stability, and maintain their mental and physical health."²² These recent interviews are consistent with the historical experience of the importance of birth control. For example, one econometric study identifies a causal relationship between the introduction and diffusion of the birth control pill and the increase in women enrolling in professional degree programs and increasing the age at first marriage.²³ As of a result of the Affordable Care Act's contraceptive coverage requirement, Title X can play a critical role, helping provide insured clients with access to contraception without cost-sharing alongside its longstanding role supporting contraceptive access without cost-sharing for Medicaid beneficiaries and those whose incomes are equal to or less than 100 percent of the federal poverty level (FPL), which allows these clients to experience these and other positive outcomes associated with access to contraception.

Researchers have identified other economic, social, and health impacts of increased access to family planning,

²¹ Jennifer J. Frost, Adam Sonfield, Mia R. Zolna, and Lawrence B. Finer (2014). "Return on Investment: a fuller assessment of the benefits and costs of the US publicly funded family planning program." *Milbank Quarterly* 2014 Dec; 92(4): 696–749.

²² Rebecca Peters, Sarah Benetar, Brigitte Courtot, and Sophia Yin (2019). "Birth Control is Transformative." Urban Institute. https://www.urban.org/sites/default/files/publication/99912/birth_control_is_transformative_1.pdf. Accessed April 6, 2021.

²³ Goldin, Claudia and Lawrence F. Katz (2002). "The power of the pill: Oral contraceptives and women's career and marriage decisions." *Journal of Political Economy* 110(4): 730–770.

contraception, and treatment. For example, Bailey et al. (2019) finds "that children born after the introduction of federal family planning programs were seven percent less likely to live in poverty and 12 percent less likely to live in households receiving public assistance." They perform an additional bounding analysis, which suggests that about two thirds of the estimated gains are due to increases in the incomes of parents.²⁴ A recent summary discusses other impacts of access to family planning services in the United States and in other countries, which extends beyond women and girls, to their children and wider communities.²⁵

The tables above present observable metrics of the effect of the Title X program, which is important for evaluating the direct effect of the program. For this reason, the scope of the analysis initially focuses on clients served and services provided by Title X-funded sites. To properly account for the net effect of the final rule when comparing the baseline scenario to the policy scenario, the Department would need to assess the extent to which clients and services continue to be provided through other channels than Title X-funded sites without the proposed rule. As a general matter, the impacts of this final rule may include:

- Transfers between grantees and prospective grantees within the Title X program;
- other transfers (for example, if Title X newly funds medical services that would, in the absence of the proposed rule, be provided by charitable organizations or other private payers); and
- societal benefits and costs to the extent that the volume or characteristics (such as location, which determines travel costs) of medical services would differ with and without the final rule.

As noted earlier in this preamble, all Planned Parenthood affiliates—which, in 2015, served 41 percent of all contraceptive clients at Title X-funded service sites—withdraw from Title X, citing the 2019 rule. However, a comparison of Planned Parenthood's two most recent annual financial reports indicates no subsequent decrease in the number of patients served and an increase, from 9.8 million to 10.4 million, in the number of services

²⁴ Bailey, Martha J., Olga Malkova, Zoë M. McLaren (2019). "Does Access to Family Planning Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X." *Journal of Human Resources* 54:4 pp. 825–856. doi:10.3368/jhr.54.4.1216–8401R1.

²⁵ Emily Sohn (2020). "Strengthening society with contraception." *Nature* 588, S162–S164.

provided per annum (pre-pandemic).²⁶ Although such year-to-year comparisons are simplistic and a focus on just one organization (even a prominent one, with extensive activities) has obvious limitations, this evidence may suggest that the Title X program impacts quantified elsewhere in this regulatory impact analysis may largely be associated with transfers.

The Department received a number of public comments drawing connections between the short-term effects of the 2019 rule and long-term potential for a reduction in total family planning clients served, not limited to the Title X program. For example, two states (NY, WA) reported receiving emergency reserve funds through state funding in order to sustain the level of care that they provided under Title X; however, both noted that this funding is not reliable and sustainable from year to year. One grantee in Maine reported keeping all clinics open and operating with the use of the association's reserve funds and through private fundraising, which was an unsustainable and impractical task to continue. Another provider also reported fundraising to maintain care while also noting the administrative burden; however, many health centers were forced to close or reduce hours due to the lack of Title X funding. The same organization also reported the need to scale back or eliminate education and outreach programs in many states. These public comments suggest that the long-term effect of the 2019 rule would have been to reduce clients served and family planning services provided beyond the Title X program.

In addition to the effects on the quantity of services, several comments discussed the effects on the quality of services provided. One organization and the Attorneys General of 22 states and the District of Columbia noted that losing Title X providers had a negative effect on patients that sought care. They argued that it was more difficult for patients to obtain culturally competent care and that the requirements of the 2019 rule placed a burden on providers and their method of pregnancy counseling, as they were "inconsistent with the standards of care and required incomplete and confusing lists and referrals for pregnant clients." Finally, several states reported that while their efforts were refocused to recruiting and

²⁶ Please see https://www.plannedparenthood.org/uploads/filer_public/2e/da/2eda3f50-82aa-4ddb-acce-c2854c4ea80b/2018-2019_annual_report.pdf and https://www.plannedparenthood.org/uploads/filer_public/67/30/67305ea1-8da2-4cee-9191-19228c1d6f70/210219-annual-report-2019-2020-web-final.pdf.

onboarding new providers into their Title X network under the 2019 rule, they faced resistance or a lack of interest, and their provider networks did not increase under the 2019 rule, continuing to adversely impact the communities they serve.

These public comments suggest that the effects identified in this regulatory impact analysis for the time horizon covering calendar year 2022 through 2026 are unlikely to be limited to a reversal of what was observed immediately after issuance of the 2019 final rule. The Department acknowledges persistent challenges with clearly disaggregating the effects that represent transfers from effects that represent benefits and costs as a result of this final rule; however, it is important to reiterate that total Title X funding remained unchanged upon issuance of the 2019 final rule and will be unchanged as a result of this final rule, so while some entities receive less funding (and they and their clients experience regulation-induced ancillary harm, which can manifest itself in the quantity or quality of associated services), other entities receive more funding. The Department maintains the analytical approach of estimating the number of additional clients served and services provided under the Title X program under this final rule, while acknowledging challenges in quantitatively assessing whether this final rule will result in additional clients served and family planning services provided, not limited to the Title X program, as compared to the baseline of no further regulatory action. Despite such uncertainty, analysis based on evidence available at this time generally supports a conclusion that the projections accompanying the 2019 rule have not been borne out.

e. Further Discussion of Distributional Effects

The Title X program is designed to provide services with priority given to persons from low-income families. According to the 2019 figures, 64 percent of clients have income under 101 percent of the federal poverty level; 14 percent between 101 percent FPL and 150 percent FPL; seven percent between 151 percent FPL to 200 percent FPL; three percent between 201 percent FPL and 250 percent FPL; seven percent over 250 percent FPL; and five percent have an unknown or unreported income level. Among program clients, 33 percent self-identified as Hispanic or Latino of all races; three percent as Asian and Not Hispanic or Latino; 22 percent as Black or African American and Not Hispanic or Latino; 32 percent as White and Not Hispanic or Latino; five percent as Other or Unknown and Not Hispanic or Latino; and four percent are Unknown or Not Reported. Furthermore, Title X requires Title X projects to provide services for adolescents without required parental consent, thereby making Title X a critical source of sexual and reproductive healthcare for young people. In 2019, two percent of program clients were younger than 15, and eight percent were younger than 18. Additional information about the number and distribution of all family planning clients by age and year are available in Exhibit A–3a of the 2019 Family Planning Annual Report. The benefits of revoking the 2019 rule would likely accrue proportionally with these income and race and ethnicity figures. The costs of revoking the 2019 rule would likely accrue proportionally to the income and other demographics of the general public.

This final rule will also likely have important geographic effects. As described in greater detail in the

Baseline section, six states currently have no Title X services, and six additional states have limited Title X services. This final rule is expected to result in restoration of services to individuals in these states.

f. Uncertainty and Sensitivity Analysis

All of the major drivers of the quantified effects of this analysis are dependent on the forecast of the baseline number of clients served. The Department acknowledges the uncertainty in this baseline and has performed a sensitivity analysis to quantify its importance. For the primary baseline, the analysis uses 2.5 million annual clients of Title X services, which corresponds to the number of clients in calendar year 2019 among remaining grantees. For its sensitivity analysis, the Department investigates the effect of the proposed rule compared to a baseline with 1.5 million clients, corresponding to the estimates for 2020. For comparison, the analysis reviewed the effects using an upper bound of 3.1 million clients served, which is the reported figure for 2019, but which includes 19 grantees, 231 subrecipients, and 945 service sites that withdrew from the Title X program following the 2019 rule.

Table F1 presents the number of clients served under different assumptions of the baseline. The analysis also recalculates the number of clients served for the final rule scenario for each of the baseline assumptions. Since the number of clients served in the first year is the midpoint between the baseline and long-run equilibrium figure, the number of clients served in 2022 under the final rule is lower for the lower-bound scenario than the primary baseline. Similarly, the number of clients served under the final rule is higher in the upper-bound scenario.

TABLE F1—TITLE X CLIENTS SERVED UNDER DIFFERENT BASELINE ASSUMPTIONS

Year	Baseline	Baseline, LB	Baseline, UB	Proposed rule	Proposed rule, LB	Proposed rule, UB
2022	2,512,066	1,536,743	3,095,666	3,247,958	2,760,296	3,539,758
2023	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2024	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2025	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2026	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849

Table F2 calculates the effect of the final rule under different baseline assumptions. These estimates are reported by year, as well as in present value and annualized for the five-year time horizon of the analysis, applying a

three percent and a seven percent discount rate. Under the lower-bound baseline scenario, the final rule will have about a 66 percent greater impact on the number of clients served in annualized terms under the primary

baseline scenario. Under the upper-bound baseline scenario, the final rule will have approximately a 64 percent lesser impact.

TABLE F2—EFFECT OF THE PROPOSED RULE ON TITLE X CLIENTS UNDER DIFFERENT BASELINE ASSUMPTIONS

Year	Proposed rule	Proposed rule, LB	Proposed rule, UB
2022	735,892	1,223,553	444,092
2023	1,471,783	2,447,106	888,183
2024	1,471,783	2,447,106	888,183
2025	1,471,783	2,447,106	888,183
2026	1,471,783	2,447,106	888,183
PDV, 3%	6,025,877	10,019,113	3,636,461
PDV, 7%	5,346,852	8,890,110	3,226,687
Annualized, 3%	1,315,778	2,187,719	794,038
Annualized, 7%	1,304,047	2,168,215	786,959

As discussed earlier, the Department acknowledges uncertainty in how quickly the Title X program will be able to restore service to levels experienced prior to the declines associated with the 2019 rule. The primary analysis adopts a two-year phase for grantees, subrecipients, service sites, and clients served to reach the long-run equilibrium estimates. If a large number of service

sites have shut down permanently, the assumption of a two-year phase-in would likely result in an overestimate of the final rule's effect over the time horizon of the analysis. Similarly, if a small number of service sites have shut down, the analysis would tend to underestimate the effect of the final rule. Therefore, as a second sensitivity analysis, the Department presents

estimates that adopt alternative assumptions about the length of time it will take to reach the long-run equilibrium estimates. Table F3 presents the primary estimates of clients served, based on a two-year phase-in, estimates without a phase-in, and estimates with a three-year phase-in assumption.

TABLE F3—TITLE X CLIENTS WITH DIFFERENT PHASE-IN ASSUMPTIONS

Year	Baseline	Proposed rule, 2-year phase-in	Proposed rule, no phase-in	Proposed rule, 3-year phase-in
2022	2,512,066	3,247,958	3,983,849	3,002,660
2023	2,512,066	3,983,849	3,983,849	3,493,255
2024	2,512,066	3,983,849	3,983,849	3,983,849
2025	2,512,066	3,983,849	3,983,849	3,983,849
2026	2,512,066	3,983,849	3,983,849	3,983,849

Table F4 calculates the effect of the final rule with different phase-in assumptions. These estimates are reported by year, as well as in present value and annualized for the five-year

time horizon of the analysis, applying a three percent and a seven percent discount rate. Compared to the primary estimates, the assumption of no phase-in yields annualized effects of the final

rule that are approximately 12 percent higher. Assuming a three-year phase-in yields annualized effects that are about 12 percent lower than the primary estimates.

TABLE F4—EFFECT OF THE PROPOSED RULE ON TITLE X CLIENTS WITH DIFFERENT PHASE-IN ASSUMPTIONS

Year	Proposed rule, 2-year phase-in	Proposed rule, no phase-in	Proposed rule, 3-year phase-in
2022	735,892	1,471,783	490,594
2023	1,471,783	1,471,783	981,189
2024	1,471,783	1,471,783	1,471,783
2025	1,471,783	1,471,783	1,471,783
2026	1,471,783	1,471,783	1,471,783
PDV, 3%	6,025,877	6,740,335	5,325,293
PDV, 7%	5,346,852	6,034,601	4,689,098
Annualized, 3%	1,315,778	1,471,783	1,162,802
Annualized, 7%	1,304,047	1,471,783	1,143,627

g. Analysis of Regulatory Alternatives to the Proposed Rule

The Department analyzed two alternatives to the approach under the final rule. The Department considered one option to maintain many elements of the 2019 rule and to impose additional restrictions on grantees. This

approach would exacerbate the trends of reduced Title X grantees, subrecipients, service sites, and clients served that we have observed under the 2019 rule. Second, the Department considered revising the 2019 rule by readopting many elements of the 2000 regulations, but adopting additional flexibilities for

grantees and reducing programmatic oversight. However, experience suggests the compliance regime as it existed prior to the 2019 rule was effective.

IV. Environmental Impact

The Department has determined under 21 CFR 25.30(k) that this action

is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act

This final rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. No public comments were provided on the proposed information collections for § 59.4, 59.5, and 59.7 proposed in the NPRM. OMB filed comment on this NPRM and assigned OMB Control Number 0970–0211. As previously stated in the preamble, the final rule is revoking the 2019 final rule in its entirety. As a result, the final rule does not include information data collection required under § 59.5(a)(12) to provide documentation or assurance to HHS of a plan to comply with state notification laws, and it does not include the

requirement under § 59.5(a)(13) to report information to HHS on subrecipients. However, additional information collection was identified related to § 59.4, 59.5, and 59.7. The final rule is revising the information collections to reflect the additional estimated burden for the Title X grant requirements under § 59.4, 59.5, and 59.7. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1.

§ 59.4 requires Title X grant applicants to describe how the proposed project would satisfy the regulatory requirements for the Title X program in their applications, including the specific project requirements under § 59.5 and the grant review criteria specified under § 59.7. We estimate that the time necessary for each Title X applicant to include this information in their grant applications would be 70 hours. All other reporting burden associated with grant applications is already approved via existing *Grants.gov* common forms.

Burden of Response: The Department is committed to leveraging existing grant, contract, annual reporting, and other Departmental forms where possible, rather than creating additional, separate forms for recipients to sign. The burden for describing the Title X grant requirements is the cost for each applicant to include this information in their grant applications. The labor cost would consist of a medical and health service manager spending an average of 70 hours writing and incorporating the Title X program information in their grant applications. The Department estimates the number of applicants at 136, based on the number of eligible applicants who applied to the Title X national grant competition before the 2019 final rule was in effect. The mean hourly wage (not including benefits and overhead) is \$55.37 per hour for the medical and health service manager.²⁷ The labor cost per application is \$3,875.90. (\$55.37 × 70 hours), and the total labor cost is \$527,122.40 (\$3,875.90 × 136 applications).

TABLE 1—ESTIMATED BURDEN FOR DESCRIBING THE TITLE X GRANT REQUIREMENTS IN THE GRANT APPLICATION FOLLOWING PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Applicant responses	Hourly rate (\$)	Burden per response (hours)	Total annual burden (hours)	Labor cost of application (\$)
Title X Grant Requirements	0970–0211	136	55.37	70	9,520	527,122.40
Total cost	527,122.40

List of Subjects in 42 CFR Part 59

Family planning, Grant programs—health, Health professions, Abortion, Birth control, Title X.

Xavier Becerra,

Secretary, Department of Health and Human Services.

42 CFR Part 59

PART 59—GRANTS FOR FAMILY PLANNING

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is revised to read as follows:

Subpart A—Project Grants for Family Planning Services

Sec.

59.1 To what programs do these regulations apply?

59.2 Definitions.

59.3 Who is eligible to apply for a family planning services grant?

59.4 How does one apply for a family planning services grant?

59.5 What requirements must be met by a family planning project?

59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

59.8 How is a grant awarded?

59.9 For what purposes may grant funds be used?

59.10 Confidentiality.

59.11 Additional conditions.

Authority: 42 U.S.C. 300a-4.

Subpart A—Project Grants for Family Planning Services

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health

Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

Clinical services provider includes physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related

²⁷ 2019 labor costs for medical and health service managers, <https://www.bls.gov/oes/2019/may/oes119111.htm>.

preventive health, and basic infertility care.

Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.

Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Family planning services include a broad range of medically approved services, which includes Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

Health equity is when all persons have the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

Inclusive is when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.

Secretary means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service site is a clinic or other location where Title X services are provided to clients. Title X recipients and/or their subrecipients may have service sites.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, et al.), the Marshall Islands, the Federated State of Micronesia, and the Republic of Palau.

Trauma-informed means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain

- (1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;
- (2) A budget and justification of the amount of grant funds requested;
- (3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and
- (4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.¹

(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

(4) Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning.² A project must:

(i) Offer pregnant clients the opportunity to be provided information

¹ 42 U.S.C. 300a-8 provides that any officer or employee of the United States, officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.

² Providers may separately be covered by federal statutes protecting conscience and/or civil rights.

and counseling regarding each of the following options:

- (A) Prenatal care and delivery;
 - (B) Infant care, foster care, or adoption; and
 - (C) Pregnancy termination.
- (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and, referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to clients from low-income families.

(7) Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(i) Family income should be assessed before determining whether copayments or additional fees are charged.

(ii) With regard to insured clients, clients whose family income is at or below 250 percent of the FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

(9) Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.

(10) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed

under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required.

(11)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for opportunities for community education, participation, and engagement to:

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a clinical services

provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or their designee on the project staff.

(8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The committee shall consist of no fewer than five members and up to as many members the recipient

determines, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of clients, and, in particular, the number of low-income clients to be served;

(2) The extent to which family planning services are needed locally;

(3) The ability of the applicant to advance health equity;

(4) The relative need of the applicant;

(5) The capacity of the applicant to make rapid and effective use of the federal assistance;

(6) The adequacy of the applicant's facilities and staff;

(7) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

(8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of an estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re compete for funds. This anticipated period will usually be for three to five years.

(b) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved

application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75.

§ 59.10 Confidentiality.

(a) All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.

(b) To the extent practical, Title X projects shall encourage family participation.³ However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

§ 59.11 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to, at the time of, or during any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[FR Doc. 2021-21542 Filed 10-4-21; 4:15 pm]

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³ 42 U.S.C. 300(a).

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